SUBCHAPTER G—OCCUPATIONAL SAFETY AND HEALTH RESEARCH AND RELATED ACTIVITIES

PART 80—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

Subparts A–C [Reserved]

Subpart D—Tuition Fees for Direct Training

Subparts A–C [Reserved]

Subpart D—Tuition Fees for Direct Training

AUTHORITY: Sec. 501, 65 Stat. 290; 31 U.S.C. 483a.

SOURCE: 38 FR 16645, June 25, 1973, unless otherwise noted.

Subparts A–C [Reserved]

§ 80.41 Applicability.

The provisions of this subpart set forth the policies of the National Institute for Occupational Safety and Health with respect to its charging fees for direct training in occupational safety or health.

§ 80.42 Definitions.

Any term not defined herein shall have the same meaning as given it in the act. As used in this subpart:

(a) *Act* means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*).

(b) *Direct training* means all technical training courses conducted directly by NIOSH for personnel of State and local governmental agencies, other Federal agencies, private industries, universities, and other non-NIOSH agencies and organizations.

(c) *NIOSH* or *Institute* means the National Institute for Occupational Safety and Health.

(d) *Registration Office* means the Direct Training Registration Office, NIOSH, 1014 Broadway, Cincinnati, OH 45202.

§ 80.43 Tuition fees.

In accordance with the provisions of the subpart, the National Institute for Occupational Safety and Health will charge fees for all students attending NIOSH direct training courses which commence on or after July 1, 1973.

§ 80.44 Schedule of fees.

(a) Tuition fees will be computed on the basis of the cost to the Government for the Institute's participation in the course, as determined by the Director of the Institute.

(b) Total tuition charges for each course will be set forth in the course announcement.

§ 80.45 Procedure for payment.

(a) Applications for direct training courses shall be completed and submitted to the registration office in accordance with the instructions issued by that office.

(b) Federal agency personnel shall, upon notification of their acceptance, submit a letter identifying the agency and office to be billed, the agency order number, and any code numbers or other information necessary for billing purposes.

(c) All other applicants shall, upon notification of their acceptance by NIOSH, submit a check payable to the National Institute for Occupational Safety and Health in the amount indicated by the course announcement prior to the commencement of the training course.

§ 80.46 Refunds.

An applicant may withdraw his application and receive full reimbursement of the fee provided that written notification to the registration office is mailed no later than 10 days before the commencement of the course for which registration has been submitted.

PART 81—GUIDELINES FOR DETERMINING PROBABILITY OF CAUSATION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000

Subpart A—Introduction

Subpart B—Definitions

Subpart C—Data Required To Estimate Probability of Causation

Subpart D—Requirements for Risk Models Used To Estimate Probability of Causation

Subpart E—Guidelines To Estimate Probability of Causation

AUTHORITY: 42 U.S.C. 7384n(c); E.O. 13179, 65 FR 77487, 3 CFR, 2000 Comp., p. 321.

SOURCE: 67 FR 22309, May 2, 2002, unless otherwise noted.

Subpart A—Introduction

§ 81.0 Background.

The Energy Employees Occupational Illness Compensation Program Act (EEOICPA), 42 U.S.C. 7384–7385 [1994, supp. 2001], provides for the payment of compensation benefits to covered employees and, where applicable, survivors of such employees, of the United States Department of Energy, its predecessor agencies and certain of its contractors and subcontractors. Among the types of illnesses for which compensation may be provided are cancers. There are two categories of covered employees with cancer under EEOICPA for whom compensation may be provided. The regulations that follow under this part apply only to the category of employees described under paragraph (a) of this section.

(a) One category is employees with cancer for whom probability of causation must be estimated or determined, as required under 20 CFR 30.115.

(b) The second category is members of the Special Exposure Cohort seeking compensation for a specified cancer, as defined under EEOICPA. The U.S. Department of Labor (DOL) which has primary authority for implementing EEOICPA, has promulgated regulations at 20 CFR 30.210 *et seq.* that identify current members of the Special Exposure Cohort and requirements for compensation. Pursuant to section 7384(q) of EEOICPA, the Secretary of HHS is authorized to add additional classes of employees to the Special Exposure Cohort.

§ 81.1 Purpose and Authority.

(a) The purpose of this regulation is to establish guidelines DOL will apply to adjudicate cancer claims for covered employees seeking compensation for cancer, other than as members of the Special Exposure Cohort seeking compensation for a specified cancer. To award a claim, DOL must first determine that it is at least as likely as not that the cancer of the employee was caused by radiation doses incurred by the employee in the performance of duty. These guidelines provide the procedures DOL must apply and identify the information DOL will use.

(b) Section 7384(n)(b) of EEOICPA requires the President to promulgate these guidelines. Executive Order 13179 assigned responsibility for promulgating these guidelines to the Secretary of HHS.

§81.2 Provisions of EEOICPA concerning this part.

EEOICPA imposes several general requirements concerning the development of these guidelines. It requires that the guidelines produce a determination as to whether it is at least as likely as not (a 50% or greater probability) that the cancer of the covered employee was related to radiation doses incurred by the employee in the performance of duty. It requires the guidelines be based on the radiation dose received by the employee, incorporating the methods of dose reconstruction to be established by HHS. It requires determinations be based on the upper 99 percent confidence interval (credibility limit) of the probability of causation in the RadioEpidemiological tables published under section 7(b) of the Orphan Drug Act (42 U.S.C. 241 note), as such tables may be updated. EEOICPA also requires HHS consider the type of cancer, past health-related activities, the risk of developing a radiation-related cancer from workplace exposure, and other relevant factors. Finally, it is important to note EEOICPA does not include a requirement limiting the types of cancers to be considered radiogenic for these guidelines.

Subpart B—Definitions

§81.4 Definition of terms used in this part.

(a) Covered employee, for purposes of this part, means an individual who is or was an employee of DOE, a DOE contractor or subcontractor, or an atomic weapons employer, and for whom DOL has requested HHS to perform a dose reconstruction.

(b) *Dose and dose rate effectiveness factor (DDREF)* means a factor applied to a risk model to modify the dose-risk relationship estimated by the model to account for the level of the dose and the rate at which the dose is incurred. As used in IREP, a DDREF value of greater than one implies that chronic or low doses are less carcinogenic per unit of dose than acute or higher doses.

(c) *Dose-response relationship* means a mathematical expression of the way that the risk of a biological effect (for example, cancer) changes with increased exposure to a potential health hazard (for example, ionizing radiation).

(d) *EEOICPA* means the Energy Employees Occupational Illness Compensation Program Act of 2000, 42 U.S.C. §§7384–7385 [1994, supp. 2001].

(e) *Equivalent dose* means the absorbed dose in a tissue or organ multiplied by a radiation weighting factor to account for differences in the effectiveness of the radiation in inducing cancer.

(f) *External dose* means the portion of the equivalent dose that is received from radiation sources outside of the body.

(g) *Interactive RadioEpidemiological Program (IREP)* means a computer software program that uses information on the dose-response relationship, and specific factors such as a claimant's radiation exposure, gender, age at diagnosis, and age at exposure to calculate the probability of causation for a given pattern and level of radiation exposure.

(h) *Internal dose* means the portion of the equivalent dose that is received from radioactive materials taken into the body.

(i) *Inverse dose rate effect* means a phenomenon in which the protraction of an exposure to a potential health hazard leads to greater biological effect per unit of dose than the delivery of the same total amount in a single dose. An inverse dose rate effect implies that the dose and dose rate effectiveness factor (DDREF) is less than one for chronic or low doses.

(j) *Linear energy transfer (LET)* means the average amount of energy transferred to surrounding body tissues per unit of distance the radiation travels through body tissues (track length). Low LET radiation is typified by gamma and x rays, which have high penetrating capabilities through various tissues, but transfer a relatively small amount of energy to surrounding tissue per unit of track length. High LET radiation includes alpha particles and neutrons, which have weaker penetrating capability but transfer a larger amount of energy per unit of track length.

(k) *NIOSH* means the National Institute for Occupational Safety and Health, Centers for Disease Control and

Prevention, United States Department of Health and Human Services.

(l) *Non-radiogenic cancer* means a type of cancer that HHS has found not to be caused by radiation, for the purposes of this regulation.

(m) *Primary cancer* means a cancer defined by the original body site at which the cancer was incurred, prior to any spread (metastasis) to other sites in the body.

(n) *Probability of causation* means the probability or likelihood that a cancer was caused by radiation exposure incurred by a covered employee in the performance of duty. In statistical terms, it is the cancer risk attributable to radiation exposure divided by the sum of the baseline cancer risk (the risk to the general population) plus the cancer risk attributable to the radiation exposure.

(o) *RadioEpidemiological Tables* means tables that allow computation of the probability of causation for various cancers associated with a defined exposure to radiation, after accounting for factors such as age at exposure, age at diagnosis, and time since exposure.

(p) *Relative biological effectiveness (RBE)* means a factor applied to a risk model to account for differences between the amount of cancer effect produced by different forms of radiation. For purposes of EEOICPA, the RBE is considered equivalent to the radiation weighting factor.

(q) *Risk model* means a mathematical model used under EEOICPA to estimate a specific probability of causation using information on radiation dose, cancer type, and personal data (e.g., gender, smoking history).

(r) *Secondary site* means a body site to which a primary cancer has spread (metastasized).

(s) *Specified cancer* is a term defined in §7384(l)(17) of EEOICPA and 20 CFR 30.5(dd) that specifies types of cancer that, pursuant to 20 CFR part 30, may qualify a member of the Special Exposure Cohort for compensation. It includes leukemia (other than chronic lymphocytic leukemia), multiple myeloma, non-Hodgkin's lymphoma, renal cancers, and cancers of the lung (other than carcinoma in situ diagnosed at autopsy), thyroid, male breast, female breast, esophagus, stomach, pharynx, small intestine, pancreas, bile ducts, gall bladder, salivary gland, urinary bladder, brain, colon, ovary, liver (not associated with cirrhosis or hepatitis B), and bone.

(t) *Uncertainty* is a term used in this rule to describe the lack of precision of a given estimate, the extent of which depends upon the amount and quality of the evidence or data available.

(u) *Uncertainty distribution* is a statistical term meaning a range of discrete or continuous values arrayed around a central estimate, where each value is assigned a probability of being correct.

(v) *Upper 99 percent confidence interval* is a term used in EEOICPA to mean credibility limit, the probability of causation estimate determined at the 99th percentile of the range of uncertainty around the central estimate of probability of causation.

Subpart C—Data Required To Estimate Probability of Causation

§ 81.5 Use of personal and medical information.

Determining probability of causation may require the use of the following personal and medical information provided to DOL by claimants under DOL regulations 20 CFR part 30:

(a) Year of birth

(b) Cancer diagnosis (by ICD–9 code) for primary and secondary cancers

(c) Date of cancer diagnosis

(d) Gender

(e) Race/ethnicity (if the claim is for skin cancer or a secondary cancer for which skin cancer is a likely primary cancer)

(f) Smoking history (if the claim is for lung cancer or a secondary cancer for which lung cancer is a likely primary cancer)

§ 81.6 Use of radiation dose information.

Determining probability of causation will require the use of radiation dose information provided to DOL by the National Institute for Occupational Safety and Health (NIOSH) under HHS regulations 42 CFR part 82. This information will include annual dose estimates for each year in which a dose was incurred, together with uncertainty distributions associated with

each dose estimate. Dose estimates will be distinguished by type of radiation (low linear energy transfer (LET), protons, neutrons, alpha, low-energy x-ray) and by dose rate (acute or chronic) for external and internal radiation dose.

Subpart D—Requirements for Risk Models Used To Estimate Probability of Causation

§81.10 Use of cancer risk assessment models in NIOSH IREP.

(a) The risk models used to estimate probability of causation for covered employees under EEOICPA will be based on risk models updated from the 1985 NIH Radioepidemiological Tables. These 1985 tables were developed from analyses of cancer mortality risk among the Japanese atomic bomb survivor cohort. The National Cancer Institute (NCI) and Centers for Disease Control and Prevention (CDC) are updating the tables, replacing them with a sophisticated analytic software program. This program, the Interactive RadioEpidemiological Program (IREP)[1], models the dose-response relationship between ionizing radiation and 33 cancers using morbidity data from the same Japanese atomic bomb survivor cohort. In the case of thyroid cancer, radiation risk models are based on a pooled analysis of several international cohorts[1a].

(b) NIOSH will change the risk models in IREP, as needed, to reflect the radiation exposure and disease experiences of employees covered under EEOICPA, which differ from the experiences of the Japanese atomic bomb survivor cohort. Changes will be incorporated in a version of IREP named NIOSH–IREP, specifically designed for adjudication of claims under EEOICPA. Possible changes in IREP risk models include the following:

(1) Addition of risk models to IREP, as needed, for claims under EEOICPA (e.g., malignant melanoma and other skin cancers)

(2) Modification of IREP risk models to incorporate radiation exposures unique to employees covered by EEOICPA (e.g., radon and low energy x rays from employer-required medical screening programs, adjustment of relative biological effectiveness distributions based on neutron energy).

(3) Modification of IREP risk models to incorporate new understanding of radiation-related cancer effects relevant to employees covered by EEOICPA (e.g., incorporation of inverse dose-rate relationship between high LET radiation exposures and cancer; adjustment of the low-dose effect reduction factor for acute exposures).

(4) Modification of IREP risk models to incorporate new understanding of the potential interaction between cancer risk associated with occupational exposures to chemical carcinogens and radiation-related cancer effects.

(5) Modification of IREP risk models to incorporate temporal, race and ethnicity-related differences in the frequency of certain cancers occurring generally among the U.S. population.

(6) Modifications of IREP to facilitate improved evaluation of the uncertainty distribution for the probability of causation for claims based on two or more primary cancers.

§81.11 Use of uncertainty analysis in NIOSH–IREP.

(a) EEOICPA requires use of the uncertainty associated with the probability of causation calculation, specifically requiring the use of the upper 99% confidence interval (credibility limit) estimate of the probability of causation estimate. As described in the NCI document,[2] uncertainty from several sources is incorporated into the probability of causation calculation performed by NIOSH–IREP. These sources include uncertainties in estimating: radiation dose incurred by the covered employee; the radiation dose-cancer relationship (statistical uncertainty in the specific cancer risk

[1] NIOSH–IREP is available for public review on the NIOSH homepage at: www.cdc.gov/niosh/ocas/ocasirep/html.

[1a] Ron E, Lubin JH, Shore RE, et al. "Thyroid cancer after exposure to external radiation: a pooled analysis of seven studies." Radiat. Res. 141:259–277, 1995.

[2] Draft Report of the NCI–CDC Working Group to Revise the 1985 NIH Radioepidemiological Tables, May 31, 2000, p. 17–18, p. 22–23.

model); the extrapolation of risk (risk transfer) from the Japanese to the U.S. population; differences in the amount of cancer effect caused by different radiation types (relative biological effectiveness or RBE); the relationship between the rate at which a radiation dose is incurred and the level of cancer risk produced (dose and dose rate effectiveness factor or DDREF); and, the role of non-radiation risk factors (such as smoking history).

(b) NIOSH–IREP will operate according to the same general protocol as IREP for the analysis of uncertainty. It will address the same possible sources of uncertainty affecting probability of causation estimates, and in most cases will apply the same assumptions incorporated in IREP risk models. Different procedures and assumptions will be incorporated into NIOSH–IREP as needed, according to the criteria outlined under §81.10.

§81.12 Procedure to update NIOSH–IREP.

(a) NIOSH may periodically revise NIOSH–IREP to add, modify, or replace cancer risk models, improve the modeling of uncertainty, and improve the functionality and user-interface of NIOSH–IREP.

(b) Revisions to NIOSH–IREP may be recommended by the following sources:

(1) NIOSH,

(2) The Advisory Board on Radiation and Worker Health,

(3) Independent reviews of NIOSH–IREP or elements thereof by scientific organizations (e.g., National Academy of Sciences),

(4) DOL,

(5) Public comment.

(c) NIOSH will submit substantive changes to NIOSH–IREP (changes that would substantially affect estimates of probability of causation calculated using NIOSH–IREP, including the addition of new cancer risk models) to the Advisory Board on Radiation and Worker Health for review. NIOSH will obtain such review and address any recommendations of the review before completing and implementing the change.

(d) NIOSH will inform the public of proposed changes provided to the Advisory Board for review. HHS will provide instructions for obtaining relevant materials and providing public comment in the notice announcing the Advisory Board meeting, published in the FEDERAL REGISTER.

(e) NIOSH will publish periodically a notice in the FEDERAL REGISTER informing the public of proposed substantive changes to NIOSH–IREP currently under development, the status of the proposed changes, and the expected completion dates.

(f) NIOSH will notify DOL and publish a notice in the FEDERAL REGISTER notifying the public of the completion and implementation of substantive changes to NIOSH–IREP. In the notice, NIOSH will explain the effect of the change on estimates of probability of causation and will summarize and address relevant comments received by NIOSH.

(g) NIOSH may take into account other factors and employ other procedures than those specified in this section, if circumstances arise that require NIOSH to implement a change more immediately than the procedures in this section allow.

Subpart E—Guidelines To Estimate Probability of Causation

§81.20 Required use of NIOSH–IREP.

(a) NIOSH–IREP is an interactive software program for estimating probability of causation for covered employees seeking compensation for cancer under EEOICPA, other than as members of the Special Exposure Cohort seeking compensation for a specified cancer.

(b) DOL is required to use NIOSH–IREP to estimate probability of causation for all cancers, as identified under §§81.21 and 81.23.

§81.21 Cancers requiring the use of NIOSH–IREP.

(a) DOL will calculate probability of causation for all cancers, except chronic lymphocytic leukemia as provided under §81.30, using NIOSH–IREP.

(b) Carcinoma in situ (ICD–9 codes 230–234), neoplasms of uncertain behavior (ICD–9 codes 235–238), and neoplasms of unspecified nature (ICD–9 code 239) are assumed to be malignant,

for purposes of estimating probability of causation.

(c) All secondary and unspecified cancers of the lymph node (ICD–9 code 196) shall be considered secondary cancers (cancers resulting from metastasis of cancer from a primary site). For claims identifying cancers of the lymph node, Table 1 in §81.23 provides guidance for assigning a primary site and calculating probability of causation using NIOSH–IREP.

§ 81.22 General guidelines for use of NIOSH–IREP.

DOL will use procedures specified in the NIOSH–IREP Operating Guide to calculate probability of causation estimates under EEOICPA. The guide provides current, step-by-step instructions for the operation of IREP. The procedures include entering personal, diagnostic, and exposure data; setting/confirming appropriate values for variables used in calculations; conducting the calculation; and, obtaining, evaluating, and reporting results.

§ 81.23 Guidelines for cancers for which primary site is unknown.

(a) In claims for which the primary cancer site cannot be determined, but a site of metastasis is known, DOL will calculate probability of causation estimates for various likely primary sites. Table 1, below, indicates the primary cancer site(s) DOL will use in NIOSH–IREP when the primary cancer site is unknown.

TABLE 1

Primary cancers (ICD–9 codes[3]) for which probability of causation is to be calculated, if only a secondary cancer site is known. "M" indicates cancer site should be used for males only, and "F" indicates the cancer site should be used for females only. A glossary of cancer descriptions for each ICD–9 code is provided in Appendix A to this part.

Secondary cancer (ICD–9 code)	ICD–9 code of likely primary cancers
Lymph nodes of head, face and neck (196.0).	141, 142 (M), 146 (M), 149 (F), 161 (M), 162, 172, 173, 174 (F), 193 (F).
Intrathoracic lymph nodes (196.1)	150 (M), 162, 174 (F).
Intra-abdominal lymph nodes (196.2)	150 (M), 151 (M), 153, 157 (F), 162, 174 (F), 180 (F), 185 (M), 189, 202 (F).
Lymph nodes of axilla and upper limb (196.3).	162, 172, 174 (F).
Inguinal and lower limb lymph nodes (196.5).	154 (M), 162, 172, 173 (F), 187 (M).
Intrapelvic lymph nodes (196.6)	153 (M), 154 (F), 162 (M), 180 (F), 182 (F), 185 (M), 188.
Lymph nodes of multiple sites (196.8)	150 (M), 151 (M), 153 (M), 162, 174 (F).
Lymph nodes, site unspecified (196.9)	150 (M), 151, 153, 162, 172, 174 (F), 185 (M).
Lung (197.0)	153, 162, 172 (M), 174 (F), 185 (M), 188 (M), 189.
Mediastinum (197.1)	150 (M), 162, 174 (F).
Pleura (197.2)	150 (M), 153 (M), 162, 174 (F), 183 (F), 185 (M), 189 (M).
Other respiratory organs (197.3)	150, 153 (M), 161, 162, 173 (M), 174 (F), 185 (M), 193 (F).
Small intestine, including duodenum (197.4).	152, 153, 157, 162, 171, 172 (M), 174 (F), 183 (F), 189 (M).
Large intestine and rectum (197.5)	153, 154, 162, 174 (F), 183 (F), 185 (M).
Retroperitoneum and peritoneum (197.6)	151, 153, 154 (M), 157, 162 (M), 171, 174 (F), 182 (F), 183 (F).
Liver, specified as secondary (197.7)	151 (M), 153, 154 (M), 157, 162, 174 (F).
Other digestive organs (197.8)	150 (M), 151, 153, 157, 162, 174 (F), 185 (M).
Kidney (198.0)	153, 162, 174 (F), 180 (F), 185 (M), 188, 189, 202 (F).
Other urinary organs (198.1)	153, 174 (F), 180 (F), 183 (F), 185 (M), 188, 189 (F).
Skin (198.2)	153, 162, 171 (M), 172, 173 (M), 174 (F), 189 (M).
Brain and spinal cord (198.3)	162, 172 (M), 174 (F).
Other parts of nervous system (198.4)	162, 172 (M), 174 (F), 185 (M), 202.
Bone and bone marrow (198.5)	162, 174 (F), 185 (M).
Ovary (198.6)	153 (F), 174 (F), 183 (F).
Suprarenal gland (198.7)	153 (F), 162, 174 (F).
Other specified sites (198.8)	153, 162, 172 (M), 174 (F), 183 (F), 185 (M), 188 (M).

[3] The International Classification of Diseases Clinical Modification (9th Revision) Volume I&II. [1991] Department of Health and Human Services Publication No. (PHS) 91–1260, U.S. Government Printing Office, Washington D.C.

(b) DOL will select the site producing the highest estimate for probability of causation to adjudicate the claim.

§ 81.24 Guidelines for leukemia.

(a) For claims involving leukemia, DOL will calculate one or more probability of causation estimates from up to three of the four alternate leukemia risk models included in NIOSH–IREP, as specified in the NIOSH–IREP Operating Guide. These include: "Leukemia, all types except CLL" (IDC–9 codes: 204–208, except 204.1), "acute lymphocytic leukemia" (ICD–9 code: 204.0), and "acute myelogenous leukemia" (ICD–9 code: 205.0).

(b) For leukemia claims in which DOL calculates multiple probability of causation estimates, as specified in the NIOSH–IREP Operating Guide, the probability of causation estimate DOL assigns to the claim will be based on the leukemia risk model producing the highest estimate for probability of causation.

§ 81.25 Guidelines for claims including two or more primary cancers.

For claims including two or more primary cancers, DOL will use NIOSH–IREP to calculate the estimated probability of causation for each cancer individually. Then DOL will perform the following calculation using the probability of causation estimates produced by NIOSH–IREP:

EQUATION 1

Calculate: $1-[\{1-PC_1\} \times \{1-PC_2\} \times . . . \times \{1-PC_n\}] = PC_{total}$,

where PC_1 is the probability of causation for one of the primary cancers identified in the claim, PC_2 is the probability of causation for a second primary cancer identified in the claim, and PC_n is the probability of causation for the nth primary cancer identified in the claim. PC_{total} is the probability that at least one of the primary cancers (cancers 1 through "n") was caused by the radiation dose estimated for the claim when Equation 1 is evaluated based on the joint distribution of $PC_1, . . ., PC_n$.[4] DOL will use the probability of causation value calculated for PC_{total} to adjudicate the claim.

[67 FR 22309, May 2, 2002; 67 FR 62096, Oct. 3, 2002]

§ 81.30 Non-radiogenic cancers

The following cancers are considered non-radiogenic for the purposes of EEOICPA and this part. DOL will assign a probability of causation of zero to the following cancers:

(a) Chronic lymphocytic leukemia (ICD–9 code: 204.1)

(b) [Reserved]

APPENDIX A TO PART 81—GLOSSARY OF ICD–9 CODES AND THEIR CANCER DESCRIPTIONS [1]

ICD–9 code	Cancer description
140	Malignant neoplasm of lip.
141	Malignant neoplasm of tongue.
142	Malignant neoplasm of major salivary glands.
143	Malignant neoplasm of gum.
144	Malignant neoplasm of floor of mouth.
145	Malignant neoplasm of other and unspecified parts of mouth.
146	Malignant neoplasm of oropharynx.
147	Malignant neoplasm of nasopharynx.
148	Malignant neoplasm of hypopharynx.
149	Malignant neoplasm of other and ill-defined sites within the lip, oral cavity, and pharynx.
150	Malignant neoplasm of esophagus.
151	Malignant neoplasm of stomach.
152	Malignant neoplasm of small intestine, including duodenum.
153	Malignant neoplasm of colon.

[4] Evaluating Equation 1 based on the individual upper 99th percentiles of $PC_1, . . ., PC_n$ approximates the upper 99th percentile of PC_{total} whenever $PC_1, . . ., PC_n$ are highly related, e.g., when a common dose-reconstruction is the only non-negligible source of uncertainty in the individual PC_i's. However, this approximation can overestimate it if other sources of uncertainty contribute independently to the $PC_1, . . ., PC_n$, whereas treating the joint distribution as fully independent could substantially underestimate the upper 99th percentile of PC_{total} whenever the individual PC_i's are positively correlated.

ICD–9 code	Cancer description
154	Malignant neoplasm of rectum, rectosigmoid junction, and anus.
155	Malignant neoplasm of liver and intrahepatic bile ducts.
156	Malignant neoplasm of gall bladder and extrahepatic bile ducts.
157	Malignant neoplasm of pancreas.
158	Malignant neoplasm of retroperitoneum and peritoneum.
159	Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum.
160	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses.
161	Malignant neoplasm of larynx.
162	Malignant neoplasm of trachea, bronchus and lung.
163	Malignant neoplasm of pleura.
164	Malignant neoplasm of thymus, heart, and mediastinum.
165	Malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs.
170	Malignant neoplasm of bone and articular cartilage.
171	Malignant neoplasm of connective and other soft tissue.
172	Malignant melanoma of skin.
173	Other malignant neoplasms of skin.
174	Malignant neoplasm of female breast.
175	Malignant neoplasm of male breast.
179	Malignant neoplasm of uterus, part unspecified.
180	Malignant neoplasm of cervix uteri.
181	Malignant neoplasm of placenta.
182	Malignant neoplasm of body of uterus.
183	Malignant neoplasm of ovary and other uterine adnexa.
184	Malignant neoplasm of other and unspecified female genital organs.
185	Malignant neoplasm of prostate.
186	Malignant neoplasm of testis.
187	Malignant neoplasm of penis and other male genital organs.
188	Malignant neoplasm of urinary bladder.
189	Malignant neoplasm of kidney and other unspecified urinary organs.
190	Malignant neoplasm of eye.
191	Malignant neoplasm of brain.
192	Malignant neoplasm of other and unspecified parts of nervous system.
193	Malignant neoplasm of thyroid gland.
194	Malignant neoplasm of other endocrine glands and related structures.
195	Malignant neoplasm of other and ill-defined sites.
196	Secondary and unspecified malignant neoplasm of the lymph nodes.
197	Secondary malignant neoplasm of the respiratory and digestive organs.
198	Secondary malignant neoplasm of other tissue and organs.
199	Malignant neoplasm without specification of site.
200	Lymphosarcoma and reticulosarcoma.
201	Hodgkin's disease.
202	Other malignant neoplasms of lymphoid and histiocytic tissue.
203	Multiple myeloma and other immunoproliferative neoplasms.
204	Lymphoid leukemia
205	Myeloid leukemia.
206	Monocytic leukemia.
207	Other specified leukemia.
208	Leukemia of unspecified cell type.

[1] The International Classification of Diseases Clinical Modification (9th Revision) Volume I&II. [1991] Department of Health and Human Services Publication No. (PHS) 91–1260, U.S. Government Printing Office, Washington, D.C.

PART 82—METHODS FOR CONDUCTING DOSE RECONSTRUCTION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000

Subpart A—Introduction

Sec.

Subpart B—Definitions

Subpart C—Dose Reconstruction Process

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SOURCE: 67 FR 22330, May 2, 2002, unless otherwise noted.

Subpart A—Introduction

§ 82.0 Background information on this part.

The Energy Employees Occupational Illness Compensation Program Act (EEOICPA), 42 U.S.C. 7384–7385 [1994, supp. 2001], provides for the payment of compensation benefits to covered employees and, where applicable, survivors of such employees, of the United States Department of Energy ("DOE"), its predecessor agencies and certain of its contractors and subcontractors. Among the types of illnesses for which compensation may be provided are cancers. There are two categories of covered employees with cancer under EEOICPA for whom compensation may be provided. The regulations that follow under this part apply only to the category of employees described under paragraph (a) of this section.

(a) One category is employees with cancer for whom a dose reconstruction must be conducted, as required under 20 CFR 30.115.

(b) The second category is members of the Special Exposure Cohort seeking compensation for a specified cancer, as defined under EEOICPA. The U.S. Department of Labor (DOL) which has primary authority for implementing EEOICPA, has promulgated regulations at 20 CFR 30.210 and 30.213 that identify current members of the Special Exposure Cohort and requirements for compensation. Pursuant to section 3626 of EEOICPA, the Secretary of HHS is authorized to add additional classes of employees to the Special Exposure Cohort.

§ 82.1 What is the purpose of this part?

The purpose of this part is to provide methods for determining a reasonable estimate of the radiation dose received by a covered employee with cancer under EEOICPA, through the completion of a dose reconstruction. These methods will be applied by the National Institute for Occupational Safety and Health (NIOSH) in a dose reconstruction program serving claimants under EEOICPA, as identified under §82.0.

§ 82.2 What are the basics of dose reconstruction?

The basic principle of dose reconstruction is to characterize the radiation environments to which workers were exposed and to then place each worker in time and space within this exposure environment. Then methods are applied to translate exposure to radiation into quantified radiation doses at the specific organs or tissues relevant to the types of cancer occurring

among the workers. A hierarchy of methods is used in a dose reconstruction, depending on the nature of the exposure conditions and the type, quality, and completeness of data available to characterize the environment.

(a) If found to be complete and adequate, individual worker monitoring data, such as dosimeter readings and bioassay sample results, are given the highest priority in assessing exposure. These monitoring data are interpreted using additional data characterizing the workplace radiation exposures. If radiation exposures in the workplace environment cannot be fully characterized based on available data, default values based on reasonable and scientific assumptions may be used as substitutes. For dose reconstructions conducted in occupational illness compensation programs, this practice may include use of assumptions that represent the worst case conditions. For example, if the solubility classification of an inhaled material can not be determined, the dose reconstruction would use the classification that results in the largest dose to the organ or tissue relevant to the cancer and that is possible given existing knowledge of the material and process.

(b) If individual monitoring data are not available or adequate, dose reconstructions may use monitoring results for groups of workers with comparable activities and relationships to the radiation environment. Alternatively, workplace area monitoring data may be used to estimate the dose. As with individual worker monitoring data, workplace exposure characteristics are used in combination with workplace monitoring data to estimate dose.

(c) If neither adequate worker nor workplace monitoring data are available, the dose reconstruction may rely substantially on process description information to analytically develop an exposure model. For internal exposures, this model includes such factors as the quantity and composition of the radioactive substance (the source term), the chemical form, particle size distribution, the level of containment, and the likelihood of dispersion.

§ 82.3 What Are the Requirements for Dose Reconstruction Under EEOICPA?

(a) Dose reconstructions are to be conducted for the following covered employees with cancer seeking compensation under EEOICPA: An employee who was not monitored for exposure to radiation at DOE or Atomic Weapons Employer (AWE) facilities; an employee who was monitored inadequately for exposure to radiation at such facilities; or an employee whose records of exposure to radiation at such facility are missing or incomplete. Technical limitations of radiation monitoring technology and procedures will require HHS to evaluate each employee's recorded dose. In most, if not all cases, monitoring limitations will result in possibly undetected or unrecorded doses, which are estimated using commonly practiced dose reconstruction methods and would have to be added to the dose record.

(b) Section 7384(n)(e) of EEOICPA requires the reporting of radiation dose information resulting from dose reconstructions to the covered employees for whom claims are being adjudicated. DOE is specifically charged with this responsibility but the Department of Health and Human Services (HHS), which will be producing the dose reconstruction information, will report its findings directly to the claimant, as well as to DOL and DOE. HHS will also make available to researchers and the general public information on the assumptions, methodology, and data used in estimating radiation doses, as required by EEOICPA.

§ 82.4 How Will DOL Use the Results of the NIOSH Dose Reconstructions?

Under 42 CFR part 81, DOL will apply dose reconstruction results together with information on cancer diagnosis and other personal information provided to DOL by the claimant to calculate an estimated probability of causation. This estimate is the probability that the cancer of the covered employee was caused by radiation exposure at a covered facility of DOE or an Atomic Weapons Employer (AWE).

Subpart B—Definitions

§ 82.5 Definition of terms used in this part.

(a) *Atomic weapons employer* (AWE) means any entity, other than the United States, that:

(1) processed or produced, for use by the United States, material that emitted radiation and was used in the production of an atomic weapon, excluding uranium mining and milling; and,

(2) is designated by the Secretary of Energy as an atomic weapons employer for purposes of EEOICPA.

(b) *Bioassay* means the determination of the kinds, quantities, or concentrations, and in some cases, locations of radioactive material in the human body, whether by direct measurement or by analysis, and evaluation of radioactive material excreted or eliminated by the body.

(c) *Claimant* means the individual who has filed with the Department of Labor for compensation under EEOICPA.

(d) *Covered employee* means, for the purposes of this part, an individual who is or was an employee of DOE, a DOE contractor or subcontractor, or an atomic weapons employer, and for whom DOL has requested HHS to perform a dose reconstruction.

(e) *Covered facility* means any building, structure, or premises, including the grounds upon which such building, structure, or premise is located:

(1) In which operations are, or have been, conducted by, or on behalf of, the DOE (except for buildings, structures, premises, grounds, or operations covered by Executive Order 12344, dated February 1, 1982, pertaining to the Naval Nuclear Propulsion Program); and,

(2) With regard to which the DOE has or had:

(i) A proprietary interest; or,

(ii) Entered into a contract with an entity to provide management and operation, management and integration, environmental remediation services, construction, or maintenance services; or

(3) A facility owned by an entity designated by the Secretary of Energy as an atomic weapons employer for purposes of EEOICPA that is or was used to process or produce, for use by the United States, material that emitted radiation and was used in the production of an atomic weapon, excluding uranium mining or milling.

(f) *DOE* means the U.S. Department of Energy, and includes predecessor agencies of DOE, including the Manhattan Engineering District.

(g) *DOL* means the U.S. Department of Labor.

(h) *EEOICPA* means the Energy Employees Occupational Illness Compensation Program Act of 2000, 42 U.S.C. 7384–7385 [1994, supp. 2001].

(i) *Equivalent dose* is the absorbed dose in a tissue multiplied by a radiation weighting factor to account for differences in the effectiveness of the radiation in inducing cancer.

(j) *External dose* means that portion of the equivalent dose that is received from radiation sources outside of the body.

(k) *Internal dose* means that portion of the equivalent dose that is received from radioactive materials taken into the body.

(l) *NIOSH* means the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

(m) *Primary cancer* means a cancer defined by the original body site at which the cancer was incurred, prior to any spread (metastasis) resulting in tumors at other sites in the body.

(n) *Probability of causation* means the probability or likelihood that a cancer was caused by radiation exposure incurred by a covered employee in the performance of duty. In statistical terms, it is the cancer risk attributable to radiation exposure divided by the sum of the baseline cancer risk (the risk to the general population) plus the cancer risk attributable to the radiation exposure. This concept is further explained under 42 CFR part 81, which provides guidelines by which DOL will determine probability of causation under EEOICPA.

(o) *Radiation* means ionizing radiation, including alpha particles, beta particles, gamma rays, x rays, neutrons, protons and other particles capable of producing ions in the body. For purposes of this rule, radiation does

not include sources of non-ionizing radiation such as radio-frequency radiation, microwaves, visible light, and infrared or ultraviolet light radiation.

(p) *Specified cancer* is a term defined in Section 3621(17) of EEOICPA and 20 CFR 30.5(dd) that specifies types of cancer that, pursuant to 20 CFR part 30, may qualify a member of the Special Exposure Cohort for compensation. It includes leukemia (other than chronic lymphocytic leukemia), multiple myeloma, non-Hodgkin's lymphoma, and cancers of the lung (other than carcinoma in situ diagnosed at autopsy), thyroid, male breast, female breast, esophagus, stomach, pharynx, small intestine, pancreas, bile ducts, gall bladder, salivary gland, urinary bladder, brain, colon, ovary, liver (not associated with cirrhosis or hepatitis), and bone. Pursuant to section 2403 of Public Law 107–20, this definition will include renal cancer effective October 1, 2001.

(q) *Uncertainty distribution* is a statistical term meaning a range of discrete or continuous values arrayed around a central estimate, where each value is assigned a probability of being correct.

(r) *Worst-case assumption* is a term used to describe a type of assumption used in certain instances for certain dose reconstructions conducted under this rule. It assigns the highest reasonably possible value, based on reliable science, documented experience, and relevant data, to a radiation dose of a covered employee.

Subpart C—Dose Reconstruction Process

§ 82.10 Overview of the dose reconstruction process.

(a) Upon receipt of a claims package from the Department of Labor, as provided under 20 CFR part 30, NIOSH will request from DOE records on radiation dose monitoring and radiation exposures associated with the employment history of the covered employee. Additionally, NIOSH may compile data, and information from NIOSH records that may contribute to the dose reconstruction. For each dose reconstruction, NIOSH will include records relevant to internal and external exposures to ionizing radiation, including exposures from medical screening x rays that were required as a condition of employment.

(b) NIOSH will evaluate the initial radiation exposure record compiled to: Reconcile the exposure record with the reported employment history, as necessary; complete preliminary calculations of dose, based upon this initial record, and prepare to consult with the claimant. Any discrepancies in the employment history information will be reconciled with the assistance of DOE, as necessary.

(c) NIOSH will interview the claimant. The interview may be conducted in one or more sessions. The purpose of the interview is to:

(1) Explain the dose reconstruction process;

(2) Confirm elements of the employment history transmitted to NIOSH by DOL;

(3) Identify any relevant information on employment history that may have been omitted;

(4) Confirm or supplement monitoring information included in the initial radiation exposure record;

(5) Develop detailed information on work tasks, production processes, radiologic protection and monitoring practices, and incidents that may have resulted in undocumented radiation exposures, as necessary;

(6) Identify co-workers and other witnesses with information relevant to the radiation exposures of the covered worker to supplement or confirm information on work experiences, as necessary.

(d) NIOSH will provide a report to the claimant summarizing the findings of the interview, titled: "NIOSH Claimant Interview under EEOICPA." The report will also notify the claimant of the opportunity to contact NIOSH if necessary, by a specified date, to make any written corrections or additions to information provided by the claimant during the interview process.

(e) Information provided by the claimant will be accepted and used for dose reconstruction, providing it is reasonable, supported by substantial evidence, and is not refuted by other evidence. In assessing whether the information provided by the claimant is

supported by substantial evidence, NIOSH will consider:

(1) Consistency of the information with other information in the possession of NIOSH, from radiation safety programs, research, medical screening programs, labor union documents, worksite investigations, dose reconstructions conducted by NIOSH under EEOICPA, or other reports relating to the circumstances at issue;

(2) Consistency of the information with medical records provided by the claimant;

(3) Consistency of the information with practices or exposures demonstrated by the dose reconstruction record developed for the claimant; and,

(4) Confirmation of information by co-workers or other witnesses.

(f) NIOSH will seek to confirm information provided by the claimant through review of available records and records requested from DOE.

(g) As necessary, NIOSH will request additional records from DOE to characterize processes and tasks potentially involving radiation exposure for which dose and exposure monitoring data is incomplete or insufficient for dose reconstruction.

(h) NIOSH will review the adequacy of monitoring data and completeness of records provided by DOE. NIOSH will request certification from DOE that record searches requested by NIOSH have been completed.

(i) As necessary, NIOSH will characterize the internal and external exposure environments for parameters known to influence the dose. For internal exposures, examples of these parameters include the mode of intake, the composition of the source term (i.e., the radionuclide type and quantity), the particle size distribution and the absorption type. When it is not possible to characterize these parameters, NIOSH may use default values, when they can be established reasonably, fairly, and based on relevant science. For external exposures, the radiation type (gamma, x-ray, neutron, beta, or other charged particle) and radiation energy spectrum will be evaluated. When possible, the effect of non-uniformity and geometry of the radiation exposure will be assessed.

(j) For individual monitoring records that are incomplete, NIOSH may assign doses using techniques discussed in §82.16. Once the resulting data set is complete, NIOSH will construct an occupational exposure matrix, using the general hierarchical approach discussed in §82.2. This matrix will contain the estimated annual equivalent dose(s) to the relevant organ(s) or tissue(s), for the period from the initial date of potential exposure at a covered facility until the date the cancer was diagnosed. The equivalent dose(s) will be calculated using the current, standard radiation weighting factors from the International Commission on Radiological Protection.[1]

(k) At any point during steps of dose reconstruction described in paragraphs (f) through (j) of this section, NIOSH may determine that sufficient research and analysis has been conducted to complete the dose reconstruction. Research and analysis will be determined sufficient if one of the following three conditions is met:

(1) From acquired experience, it is evident the estimated cumulative dose is sufficient to qualify the claimant for compensation (*i.e.*, the dose produces a probability of causation of 50% or greater);

(2) Dose is determined using worst-case assumptions related to radiation exposure and intake, to substitute for further research and analyses; or,

(3) Research and analysis indicated under steps described in paragraphs (f)–(j) of this section have been completed. Worst-case assumptions will be employed under condition 2 to limit further research and analysis only for claims for which it is evident that further research and analysis will not produce a compensable level of radiation dose (a dose producing a probability of causation of 50% or greater), because using worst-case assumptions it can be determined that the employee could not have incurred a compensable level of radiation dose. For all claims in which worst-case assumptions are

[1] The current weighting factors of the International Commission on Radiological Protection are provided in ICRP 60: "1990 Recommendations of the International Commission on Radiological Protection." Ann. ICRP 21 (1–3):6.

employed under condition 2, the reasoning that resulted in the determination to limit further research and analysis will be clearly described in the draft of the dose reconstruction results reported to the claimant under §82.25 and in the dose reconstruction results reported to the claimant under §82.26.

(l) After providing the claimant with a copy of a draft of the dose reconstruction report to be provided to DOL, NIOSH will conduct a closing interview with the claimant to review the dose reconstruction results and the basis upon which the results were calculated. This will be the final opportunity during the dose reconstruction process for the claimant to provide additional relevant information that may affect the dose reconstruction. The closing interview may require multiple sessions, if the claimant requires time to obtain and provide additional information, and to allow NIOSH time to integrate the new information into a new draft of the dose reconstruction report. NIOSH will determine whether to grant requests for time to provide additional information, based on whether the requests are reasonable and the claimant is actively seeking the information specified.

(m) Subject to any additional information provided by the claimant and revision of the draft dose reconstruction report under §82.10(l), the claimant is required to return form OCAS–1 to NIOSH, certifying that the claimant has completed providing information and that the record for dose reconstruction should be closed. Upon receipt of the form, NIOSH will forward a final dose reconstruction report to DOL, DOE, and to the claimant.

(n) NIOSH will not forward the dose reconstruction report to DOL for adjudication without receipt of form OCAS–1 signed by the claimant or a representative of the claimant authorized pursuant to 20 CFR 30.600. If the claimant or the authorized representative of the claimant fails to sign and return form OCAS–1 within 60 days, or 60 days following the claimant's final provision of additional information and receipt of a revised draft dose reconstruction report under §82.10 (l), whichever occurs last, after notifying the claimant or the authorized representative, NIOSH may administratively close the dose reconstruction and notify DOL of this action. Upon receiving this notification by NIOSH, DOL may administratively close the claim.

(o) Once actions under §82.10 (m) are completed, the record for dose reconstruction shall be closed unless reopened at the request of DOL under 20 CFR part 30.

§82.11 For which claims under EEOICPA will NIOSH conduct a dose reconstruction?

NIOSH will conduct a dose reconstruction for each claim determined by DOL to be a claim for a covered employee with cancer under DOL regulations at 20 CFR 30.210(b), subject to the limitation and exception noted in §82.12. Claims for covered employees who are members of the Special Exposure Cohort seeking compensation for a specified cancer, as determined by DOL under 20 CFR 30.210(a), do not require and will not receive a dose reconstruction under this rule.

§82.12 Will it be possible to conduct dose reconstructions for all claims?

It is uncertain whether adequate information of the types outlined under §82.14 will be available to complete a dose reconstruction for every claim eligible under §82.11.

(a) NIOSH will notify in writing any claimants for whom a dose reconstruction cannot be completed once that determination is made, as well as in the closing interview provided for under §82.10(l).

(b) Notification will describe the basis for finding a dose reconstruction cannot be completed, including the following:

(1) A summary of the information obtained from DOE and other sources; and, (2) a summary of necessary information found to be unavailable from DOE and other sources.

(c) NIOSH will notify DOL and DOE when it is unable to complete a dose reconstruction for the claimant. This will result in DOL producing a recommended decision to deny the claim, since DOL cannot determine probability of causation without a dose estimate produced by NIOSH under this rule.

(d) A claimant for whom a dose reconstruction cannot be completed, as indicated under this section, may have recourse to seek compensation under provisions of the Special Exposure Cohort (see 20 CFR part 30). Pursuant to section 7384q of EEOICPA, the Secretary of HHS is authorized to add classes of employees to the Special Exposure Cohort. NIOSH will provide the claimant with any information and forms that HHS provides to classes of employees seeking to petition to be added to the Special Exposure Cohort.

§ 82.13 What sources of information may be used for dose reconstructions?

NIOSH will use the following sources of information for dose reconstructions, as necessary:

(a) DOE and its contractors, including Atomic Weapons Employers and the former worker medical screening program;

(b) NIOSH and other records from health research on DOE worker populations;

(c) Interviews and records provided by claimants;

(d) Co-workers of covered employees, or others with information relevant to the covered employee's exposure, that the claimant identified during the initial interview with NIOSH;

(e) Labor union records from unions representing employees at covered facilities of DOE or AWEs; and,

(f) Any other relevant information.

§ 82.14 What types of information could be used in dose reconstructions?

NIOSH will obtain the types of information described in this section for dose reconstructions, as necessary and available:

(a) *Subject and employment information,* including:

(1) Gender;

(2) Date of birth; and,

(3) DOE and/or AWE employment history, including: job title held by year, and work location(s): including site names(s), building numbers(s), technical area(s), and duration of relevant employment or tasks.

(b) *Worker monitoring data,* including:

(1) External dosimetry data, including external dosimeter readings (film badge, TLD, neutron dosimeters); and,

(2) Pocket ionization chamber data.

(c) *Internal dosimetry data,* including:

(1) Urinalysis results;

(2) Fecal sample results;

(3) In Vivo measurement results;

(4) Incident investigation reports;

(5) Breath radon and/or thoron results;

(6) Nasal smear results;

(7) External contamination measurements; and

(8) Other measurement results applicable to internal dosimetry.

(d) *Monitoring program data,* including:

(1) Analytical methods used for bioassay analyses;

(2) Performance characteristics of dosimeters for different radiation types;

(3) Historical detection limits for bioassay samples and dosimeter badges;

(4) Bioassay sample and dosimeter collection/exchange frequencies;

(5) Documentation of record keeping practices used to record data and/or administratively assign dose; and,

(6) Other information to characterize the monitoring program procedures and evaluate monitoring results.

(e) *Workplace monitoring data,* including:

(1) Surface contamination surveys;

(2) General area air sampling results;

(3) Breathing zone air sampling results;

(4) Radon and/or thoron monitoring results;

(5) Area radiation survey measurements (beta, gamma and neutron); and,

(6) Fixed location dosimeter results (beta, gamma and neutron); and,

(7) Other workplace monitoring results.

(f) *Workplace characterization data,* including:

(1) Information on the external exposure environment, including: radiation type (gamma, x-ray, proton, neutron, beta, other charged particle); radiation energy spectrum; uniformity of exposure (whole body vs partial body exposure); irradiation geometry;

(2) Information on work-required medical screening x rays; and,

(3) Other information useful for characterizing workplace radiation exposures.

(g) *Information characterizing internal exposures,* including:

(1) Radionuclide(s) and associated chemical forms;

(2) Results of particle size distribution studies;

(3) Respiratory protection practices; and

(4) Other information useful for characterizing internal exposures.

(h) *Process descriptions for each work location,* including:

(1) General description of the process;

(2) Characterization of the source term (i.e., the radionuclide and its quantity);

(3) Extent of encapsulation;

(4) Methods of containment;

(5) Other information to assess potential for irradiation by source or airborne dispersion radioactive material.

§ 82.15 How will NIOSH evaluate the completeness and adequacy of individual monitoring data?

(a) NIOSH will evaluate the completeness and adequacy of an individual's monitoring data provided by DOE through one or more possible measures including, but not limited to:

(1) Comparisons with information provided by claimants, co-workers, and other witnesses;

(2) Comparisons with available information on area monitoring, production processes, and radiologic protection programs;

(3) Comparisons with information documented in the records of unions representing covered employees;

(4) Comparisons with data available on co-workers; and

(5) Reviews of DOE contractor record systems.

(b) NIOSH will evaluate the instruments and procedures used to collect individual monitoring data to determine whether they adequately characterized the radiation environments in which the covered employee worked, (adequately for the purpose of dose reconstruction,) based on present-day scientific understanding. For external dosimeter measurements, this includes an evaluation of the dosimeter response to the radiation types (gamma, x-ray, neutron, beta, or other charged particle) and the associated energy spectrum. For internal exposure, the methods used to analyze bioassay samples will be reviewed to determine their ability to detect the radionuclides present in the work environment. An analysis of the monitoring or exchange frequencies for the monitoring programs will also be conducted to determine the potential for undetected dose.

§ 82.16 How will NIOSH add to monitoring data to remedy limitations of individual monitoring and missed dose?

(a) For external dosimeter results that are incomplete due to historical record keeping practices, NIOSH will use commonly practiced techniques, such as those described in the NIOSH Research Issues Workshop,[2] to estimate the missing component of dose and to add this to the total dose estimate. For monitoring periods where external dosimetry data are missing from the records, NIOSH will estimate a claimant's dose based on interpolation, using available monitoring results from other time periods close to the period in question, or based on monitoring data on other workers engaged in similar tasks.

(b) NIOSH will review historical bioassay sample detection limits and monitoring frequencies to determine, when possible, the minimum detectable dose for routine internal dose monitoring programs. This "missed dose" will establish the upper limit of internal dose that a worker could have received for periods when bioassay sample analysis results were below the detection limit. Using ICRP biokinetic models, NIOSH will estimate the internal dose and include an associated uncertainty distribution.

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[2] NIOSH [1995]. NIOSH research issues workshop: epidemiologic use of nondetectable values in radiation exposure measurements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 224647 (NTIS—PB 95189601).

§ 82.17 What types of information could be used to supplement or substitute for individual monitoring data?

Three types of information could be used:

(a) Monitoring data from co-workers, if NIOSH determines they had a common relationship to the radiation environment; or,

(b) A quantitative characterization of the radiation environment in which the covered employee worked, based on an analysis of historical workplace monitoring information such as area dosimeter readings, general area radiation and radioactive contamination survey results, air sampling data; or,

(c) A quantitative characterization of the radiation environment in which the employee worked, based on analysis of data describing processes involving radioactive materials, the source materials, occupational tasks and locations, and radiation safety practices.

§ 82.18 How will NIOSH calculate internal dose to the primary cancer site(s)?

(a) The calculation of dose from ingested, inhaled or absorbed radioactivity involves the determination of the types and quantities of radionuclides that entered the body. NIOSH will use the results of all available bioassay monitoring information as appropriate, based on assessment of the technical characteristics of the monitoring program. If bioassay monitoring data are unavailable or inadequate, the dose reconstruction will rely on the results of air sampling measurements, radiation sources, work processes and practices, and incidents involving radiation contamination, as necessary.

(b) NIOSH will calculate the dose to the organ or tissue of concern using the appropriate current metabolic models published by ICRP. Using data available to NIOSH, the models will be based on exposure conditions representative of the work environment. When NIOSH cannot establish exposure conditions with sufficient specificity, the dose calculation will assume exposure conditions that maximize the dose to the organ under consideration. When the cancer covered by a claim is in a tissue not covered by existing ICRP models, NIOSH will use the ICRP model that best approximates the model needed, while giving the benefit of the doubt to the claimant. For internal exposures, NIOSH will select the highest dose estimate from among the modeled organs or tissues that do not concentrate the radionuclide.

(c) Internal doses will be calculated for each year of exposure from the date of initial exposure to the date of cancer diagnosis.

§ 82.19 How will NIOSH address uncertainty about dose levels?

The estimate of each annual dose will be characterized with a probability distribution that accounts for the uncertainty of the estimate. This information will be used by DOL in the calculation of probability of causation, under HHS guidelines for calculating probability of causation estimates at 42 CFR 81. In this way, claimants will receive the benefit of the doubt in cases in which the actual dose may have exceeded the best estimate calculated by NIOSH.

Subpart D—Reporting and Review of Dose Reconstruction Results

§ 82.25 When will NIOSH report dose reconstruction results, and to whom?

NIOSH will report dose reconstruction results to DOL and to the claimant, as provided for under §82.10. Draft results will be reported to the claimant upon tentative completion of the dose reconstruction. Final results will be reported to the claimant, DOL and DOE after NIOSH receives certification from the claimant that the claimant has completed providing information to NIOSH for the dose reconstruction (Form OCAS–1).

§ 82.26 How will NIOSH report dose reconstruction results?

(a) NIOSH will provide dose reconstruction results to the claimant, DOL, and DOE in a report: "NIOSH Report of Dose Reconstruction under EEOICPA." The report itself will not provide information on probability of causation, which DOL must calculate to determine a recommended decision on the claim.

(b) The report will include the following information, as relevant:

(1) Annual dose estimates (or a fraction thereof) related to covered employment for each year from the date of initial radiation exposure at a covered facility to the date of cancer diagnosis;

(2) Separate dose estimates for acute and chronic exposures, different types of ionizing radiation, and internal and external doses, providing internal dose information only for the organ or tissue relevant to the primary cancer site(s) established in the claim;

(3) Uncertainty distributions associated with each dose estimated, as necessary;

(4) Explanation of each type of dose estimate included in terms of its relevance for estimating probability of causation;

(5) Identification of any information provided by the claimant relevant to dose estimation that NIOSH decided to omit from the basis for dose reconstruction, justification for the decision, and if possible, a quantitative estimate of the effect of the omission on the dose reconstruction results; and

(6) A summary and explanation of information and methods applied to produce the dose reconstruction estimates, including any factual findings and the evidence upon which those findings are based.

(c) As provided under § 82.10(l), NIOSH staff will conduct a closing interview with claimants to explain the dose reconstruction report.

§ 82.27 How can claimants obtain reviews of their NIOSH dose reconstruction results by NIOSH?

(a) Claimants can seek reviews of their dose reconstruction through the processes established by DOL under 20 CFR 30. DOL will request NIOSH to review dose reconstructions under the following conditions, as provided under 20 CFR 30.318:

(1) DOL may determine that factual findings of the dose reconstruction do not appear to be supported by substantial evidence; or,

(2) Although the methodology established by HHS under this Part is binding on DOL, DOL may determine that arguments concerning the *application* of this methodology should be considered by NIOSH.

(b) NIOSH may review completed dose reconstructions on its own initiative and with the assistance of DOL to identify denied claims when either of the following circumstances arise:

(1) NIOSH obtains records or information on radiation exposures of DOE or AWE employees that could substantially increase the level of radiation doses estimated in the completed dose reconstructions; or

(2) NIOSH changes a scientific element underlying dose reconstructions according to the provisions of Subpart E of this rule and the change could substantially increase the level of radiation doses estimated in the completed dose reconstructions.

(c) When NIOSH completes the review of a dose reconstruction, NIOSH will provide a report describing the basis for the review, the methods employed in the review, and the review findings to the claimant, DOL, and DOE.

§ 82.28 Who can review NIOSH dose reconstruction files on individual claimants?

(a) Claimants and DOL will be provided individual dose reconstruction files, upon request. Claimants should note, however, that a complete summary of the data and methods used in a dose reconstruction will be included in the "NIOSH Report of Dose Reconstruction under EEOICPA''.

(b) Researchers and the public will be provided limited access to NIOSH dose reconstruction files, subject to provisions and restrictions of the Privacy Act for the protection of confidential information on individuals.

Subpart E—Updating the Scientific Elements Underlying Dose Reconstructions

§ 82.30 How will NIOSH inform the public of any plans to change scientific elements underlying the dose reconstruction process to maintain methods reasonably current with scientific progress?

Periodically, NIOSH will publish a notice in the FEDERAL REGISTER notifying the public of plans to change scientific elements underlying the dose reconstruction process under EEOICPA to reflect scientific progress. Notice will include a summary of the planned changes and the expected completion date for such changes.

§ 82.31 How can the public recommend changes to scientific elements underlying the dose reconstruction process?

(a) At any time, the public can submit written recommendations to NIOSH for changes to scientific elements underlying the dose reconstruction process, based on relevant new research findings and technological advances. NIOSH will provide these recommendations to the Advisory Board on Radiation and Worker Health to be addressed at a public meeting of the Advisory Board, with notification provided to the source of the recommendations. Recommendations should be addressed to: Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS–R45, Cincinnati, Ohio 45226.

(b) The public can also submit recommendations by e-mail. Instructions will be provided on the NIOSH Internet homepage at www.cdc.gov/niosh/ocas.

§ 82.32 How will NIOSH make changes in scientific elements underlying the dose reconstruction process, based on scientific progress?

NIOSH will present proposed changes to the Advisory Board on Radiation and Worker Health prior to implementation. These proposed changes will be summarized in a notice published in the FEDERAL REGISTER. The public will have the opportunity to comment on proposed changes at the meeting of the Advisory Board and/or in written comments submitted for this purpose. NIOSH will fully consider the comments of the Advisory Board and of the public before deciding upon any changes.

§ 82.33 How will NIOSH inform the public of changes to the scientific elements underlying the dose reconstruction process?

(a) NIOSH will publish a notice in the FEDERAL REGISTER informing the public of changes and the rationale for the changes. This notice will also provide a summary of the recommendations and comments received from the Advisory Board and the public, as well as responses to the comments.

(b) NIOSH may take into account other factors and employ other procedures than those specified in this subpart, if circumstances arise that require NIOSH to implement a change more immediately than the procedures in this subpart allow.

PART 83—PROCEDURES FOR DESIGNATING CLASSES OF EMPLOYEES AS MEMBERS OF THE SPECIAL EXPOSURE COHORT UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000

Subpart A—Introduction

Sec.

Subpart B—Definitions

Subpart C—Procedures for Adding Classes of Employees to the Cohort

AUTHORITY: 42 U.S.C. 7384q; E.O. 13179, 65 FR 77487, 3 CFR, 2000 Comp., p. 321.

SOURCE: At 69 FR 30780, May 28, 2004, unless otherwise noted.

Subpart A—Introduction

§83.0 Background information on the procedures in this part.

The Energy Employees Occupational Illness Compensation Program Act, as amended ("EEOICPA" or "the Act"), 42 U.S.C. 7384–7385, provides for the payment of compensation benefits to covered employees and, where applicable, survivors of such employees, of DOE, its predecessor agencies and certain of its contractors and subcontractors. Among the types of illnesses for which compensation may be provided are cancers. There are two methods set forth in the statute for claimants to establish that a cancer incurred by a covered worker is compensable under EEOICPA. The first is to establish that the cancer is at least as likely as not related to covered employment at a DOE or Atomic Weapons Employer ("AWE") facility pursuant to guidelines issued by the Department of Health and Human Services ("HHS"), which are found at 42 CFR part 81. The second method to establish that a cancer incurred by a covered worker is compensable under EEOICPA is to establish that the worker is a member of the Special Exposure Cohort ("the Cohort") and suffered a specified cancer after beginning employment at a DOE facility or AWE facility. In Section 3621(14) of EEOICPA (42 U.S.C. 7384l(14)) Congress included certain classes of employees in the Cohort. Section 3626 of the Act (42 U.S.C. 7384q) authorizes the addition to the Cohort of other classes of employees. This authority has been delegated to the Secretary of HHS by Executive Order 13179.

§83.1 What is the purpose of the procedures in this part?

EEOICPA authorizes the President to add classes of employees to the Cohort, while providing Congress with the opportunity to review and expedite or reverse these decisions. The President delegated his authority to the Secretary of HHS. This part specifies the procedures by which HHS will determine whether to add new classes of employees from DOE and AWE facilities to the Cohort. HHS will consider adding new classes of employees in response to petitions by, or on behalf of, such classes of employees. The procedures specify requirements for petitions and for their consideration. These requirements are intended to ensure that petitions are submitted by authorized parties, are justified, and receive uniform, fair, scientific consideration. The procedures are also designed to give petitioners and interested parties opportunity for appropriate involvement in the process, and to ensure that the process is timely and consistent with requirements specified in EEOICPA. The procedures are not intended to provide a second opportunity to qualify a claim for compensation, once HHS has completed the dose reconstruction and DOL has determined that the cancer subject to the claim was not "at least as likely as not" caused by the estimated radiation doses. DOL has established procedures separate from those covered by this part, under 20 CFR part 30, for cancer claimants who want to contest the factual determinations or how NIOSH conducted their dose reconstructions.

§ 83.2 How will DOL use the designations established under the procedures in this part?

DOL will adjudicate compensation claims for members of classes of employees added to the Cohort according to the same general procedures that apply to the statutorily defined classes of employees in the Cohort. Specifically, DOL will determine whether the claim is for a qualified member of the Cohort with a specified cancer, pursuant to the procedures set forth in 20 CFR part 30.

Subpart B—Definitions

§ 83.5 Definitions of terms used in the procedures in this part.

(a) *Advisory Board on Radiation and Worker Health ("the Board")* is a federal advisory committee established under EEOICPA and appointed by the President to advise HHS in implementing its responsibilities under EEOICPA.

(b) *Atomic Weapons Employer ("AWE")* is a statutory term of EEOICPA which means any entity, other than the United States, that:

(1) Processed or produced, for use by the United States, material that emitted radiation and was used in the production of an atomic weapon, excluding uranium mining and milling: and,

(2) Is designated by the Secretary of Energy as an atomic weapons employer for purposes of EEOICPA.

(c) *Class of employees* means, for the purposes of this part, a group of employees who work or worked at the same DOE facility or AWE facility, and for whom the availability of information and recorded data on radiation exposures is comparable with respect to the informational needs of dose reconstructions conducted under 42 CFR part 82.

(d) *HHS* is the U.S. Department of Health and Human Services.

(e) *DOE* is the U.S. Department of Energy, which includes predecessor agencies of DOE, including the Manhattan Engineering District.

(f) *DOL* is the U.S. Department of Labor.

(g) *Employee,* for the purposes of these procedures, means a person who is or was, for the purposes of EEOICPA, an employee of DOE, a DOE contractor or subcontractor, or an Atomic Weapons Employer.

(h) *NIOSH* is the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

(i) *OCAS* is the Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

(j) *Petitioner* means an individual or organization that submits a petition on behalf of a class of employees and qualifies as a petitioner under §83.7. A single petition shall only include up to three petitioners.

(k) *Radiation* means ionizing radiation, including alpha particles, beta particles, gamma rays, x rays, neutrons, protons and other particles capable of producing ions in the body. For the purposes of the proposed procedures, radiation does not include sources of non-ionizing radiation such as radio-frequency radiation, microwaves, visible light, and infrared or ultraviolet light radiation.

(l) *Secretary* is the Secretary of Health and Human Services.

(m) *Specified cancer,* as is defined in Section 3621(17) of EEOICPA (42 U.S.C. 7384l(17)) and the DOL regulation implementing EEOICPA (20 CFR 30.5(dd)), means:

(1) Leukemia (other than chronic lymphocytic leukemia) provided that onset of the disease was at least two years after initial occupational exposure;

(2) Lung cancer (other than in situ lung cancer that is discovered during or after a post-mortem exam);

(3) Bone cancer;

(4) Renal cancers;

(5) The following diseases, provided onset was at least 5 years after first exposure:

(i) Multiple myeloma;

(ii) Lymphomas (other than Hodgkin's disease);

(iii) Primary cancer of the:

(A) Thyroid;

(B) Male or female breast;

(C) Esophagus;

(D) Stomach;

(E) Pharynx;

(F) Small intestine;
(G) Pancreas;
(H) Bile ducts;
(I) Gall bladder;
(J) Salivary gland;
(K) Urinary bladder;
(L) Brain;
(M) Colon;
(N) Ovary;
(O) Liver (except if cirrhosis or hepatitis B is indicated).

(6) The specified diseases designated in this section mean the physiological condition or conditions that are recognized by the National Cancer Institute under those names or nomenclature, or under any previously accepted or commonly used names or nomenclature.

(n) Survivor means a surviving spouse, child, parent, grandchild and grandparent of a deceased covered employee as defined in EEOICPA.

Subpart C—Procedures for Adding Classes of Employees to the Cohort

§ 83.6 Overview of the procedures in this part.

The procedures in this part specify who may petition to add a class of employees to the Cohort, the requirements for such a petition, how a petition will be selected for evaluation by NIOSH and for the advice of the Board, and the process NIOSH, the Board, and the Secretary will use to consider a petition, leading to the Secretary's final determination to accept or deny adding a class to the Cohort. The rule provides for petitions in two distinct circumstances. One circumstance is when NIOSH has attempted to conduct a dose reconstruction for a cancer claimant, under 42 CFR part 82, and finds that the dose reconstruction cannot be completed, because there is insufficient information to estimate the radiation doses of the claimant with sufficient accuracy. The second circumstance includes all other possibilities. For example, a petition may be submitted representing a class of employees whose members have yet to file claims under EEOICPA, or even have yet to be diagnosed with cancer. As required by EEOICPA (42 U.S.C. 7384l(14)(c)(ii)), the procedures in this part include formal notice to Congress of any decision by the Secretary to add a class to the Cohort, and the opportunity for Congress to expedite or change the outcome of the decision within 180 days.

§ 83.7 Who can submit a petition on behalf of a class of employees?

A petitioner or petitioners for a petition must be one or more, up to a maximum of three, of the following:

(a) One or more DOE, DOE contractor or subcontractor, or AWE employees, who would be included in the proposed class of employees, or their survivors; or

(b) One or more labor organizations representing or formerly having represented DOE, DOE contractor or subcontractor, or AWE employees, who would be included in the proposed class of employees; or

(c) One or more individuals or entities authorized in writing by one or more DOE, DOE contractor or subcontractor, or AWE employees, who would be included in the proposed class of employees, or their survivors.

§ 83.8 How is a petition submitted?

The petitioner(s) must send a petition in writing to NIOSH. A petition must provide identifying and contact information on the petitioner(s) and information to justify the petition, as specified under §83.9. Detailed instructions for preparing and submitting a petition, including an optional petition form, are available from NIOSH through direct request (1–800–35–NIOSH) or on the Internet at *www.cdc.gov/niosh/ocas.*

§ 83.9 What information must a petition include?

(a) All petitions must provide identifying and contact information on the petitioner(s). The information required to justify a petition differs, depending on the basis of the petition. If the petition is by a claimant in response to a finding by NIOSH that the dose reconstruction for the claimant cannot be completed, then the petition must provide only the justification specified under paragraph (b) of this section. All other petitions must provide only the information specified under paragraph (c) of this section. The informational requirements for petitions are also

summarized in Table 1 at the end of this section.

(b) The petition must notify NIOSH that the claimant is petitioning on the basis that NIOSH found, under 42 CFR 82.12, that the dose reconstruction for the claimant could not be completed due to insufficient records and information.

(c) The petition must include the following:

(1) A proposed class definition[1] specifying:

(i) The DOE facility or AWE facility[2] at which the class worked;

(ii) The location or locations at the facility covered by the petition (*e.g.*, building, technical area);

(iii) The job titles and/or job duties of the class members;

(iv) The period of employment relevant to the petition;

(v) Identification of any exposure incident that was unmonitored, unrecorded, or inadequately monitored or recorded, if such incident comprises the basis of the petition; and

(2) A description of the petitioner's (petitioners") basis for believing records and information available are inadequate to estimate the radiation doses incurred by members of the proposed class of employees with sufficient accuracy. This description must include one of the following elements:

(i) Documentation or statements provided by affidavit indicating that radiation exposures and doses to members of the proposed class were not monitored, either through personal or area monitoring; or

(ii) Documentation or statements provided by affidavit indicating that radiation monitoring records for members of the proposed class have been lost, falsified, or destroyed; or

(iii) A report from a health physicist or other individual with expertise in dose reconstruction documenting the limitations of existing DOE or AWE records on radiation exposures at the facility, as relevant to the petition. This report should specify the basis for believing these documented limitations might prevent the completion of dose reconstructions for members of the class under 42 CFR part 82 and related NIOSH technical implementation guidelines; or

(iv) A scientific or technical report, published or issued by a government agency of the Executive Branch of government or the General Accounting Office, the Nuclear Regulatory Commission, or the Defense Nuclear Facilities Safety Board, or published in a peer-reviewed journal, that identifies dosimetry and related information that are unavailable (due to either a lack of monitoring or the destruction or loss of records) for estimating the radiation doses of employees covered by the petition.

(3) If the petition is based on an exposure incident as described under paragraph (c)(1)(v) of this section, the petitioner(s) might be required to provide evidence that the incident occurred, but only if NIOSH is unable to obtain records or confirmation of the occurrence of such an incident from sources independent of the petitioner(s). Such evidence would not be required at the time the petition is submitted and the petitioner(s) would be directly informed of the need for this supplemental information. In such cases, either of the following may qualify as evidence:

(i) Medical evidence that one or more members of the class may have incurred a high level radiation dose from the incident, such as a depressed white blood cell count associated with radiation exposure or the application of chelation therapy; or

(ii) NIOSH will consider evidence provided by affidavit from one or more employees who witnessed the incident. If the petitioner cannot provide such affidavits because such employees are deceased, prevented by reasons of poor health or impairment, or cannot be identified or located, then the requirement for evidence provided by affidavit

[1] HHS will determine the final class definition(s) for each petition (see §83.16).

[2] Depending on the factual circumstances present, a facility that meets the definition of an AWE facility or DOE facility covered under EEOICPA (42 U.S.C. 7384l(5) and (12)) could, among other possibilities, constitute a single building or structure, including the grounds upon which it is located, or a site encompassing numerous buildings or structures, including the grounds upon which it is located.

can be met by providing such an affidavit from one or more individuals who did not witness the incident, provided the individual was directly informed by one or more employees who witnessed the incident.[3]

(4) The provision of any evidence under this section or other provisions of this part, including one or more affidavits, would not, in and of itself, be sufficient to confirm the facts presented by that evidence. NIOSH will consider the adequacy and credibility of any evidence provided.

(5) If, under § 83.15(a), NIOSH has already issued a FEDERAL REGISTER notice scheduling a Board meeting to consider a petition concerning a class of employees, then any petitions for such a class of employees submitted following this notice must, under paragraph (c)(2) of this section, present substantially new information that has not already been considered by NIOSH. For this purpose, NIOSH would find that information has been already considered by NIOSH if it were included in the petition(s) that were already considered by NIOSH or if it were addressed either in the report(s) by NIOSH evaluating such a petition or petitions under § 83.13(c) or in a proposed decision by NIOSH responding to such a petition or petitions under § 83.16(a).

TABLE 1 FOR § 83.9: SUMMARY OF INFORMATIONAL REQUIREMENTS FOR ALL PETITIONS

[Petitioner(s) must submit identifying and contact information and either A. or B. of this table.]

A. The claimant's authorization of the petition, based on NIOSH having found it could not complete a dose reconstrucitn for the claimant submitting the petition; or.	B. (1) A proposed class definition identifying: (i) Facility, (ii) relevant locations at the facility; (iii) job titles/duties, (iv) period of employment, and if relevant, (v) exposure incident. (2) The basis for infeasibility of dose reconstruction; either: (i) lack of monitoring; or (ii) destruction, falsification, or loss of records; or (iii) expert report; or (iv) scientific or technical report.

§ 83.10 If a petition satisfies all relevant requirements under § 83.9, does this mean the class will be added to the Cohort?

Satisfying the informational requirements for a petition does not mean the class will be added to the Cohort. It means the petition will receive a full evaluation by NIOSH, the Board, and HHS, as described under §§ 83.13 through 83.16. The role of the petitioner(s) is to identify classes of employees that should be considered for addition to the Cohort.

§ 83.11 What happens to petitions that do not satisfy all relevant requirements under §§ 83.7 through 83.9?

(a) NIOSH will notify the petitioner(s) of any requirements that are not met by the petition, assist the petitioner(s) with guidance in developing relevant information, and provide 30 calendar days for the petitioner(s) to revise the petition accordingly.

(b) After 30 calendar days from the date of notification under paragraph (a) of this section, NIOSH will notify any petitioner(s) whose petition remains unsatisfactory of the proposed finding of NIOSH that the petition fails to meet the specified requirements and the basis for this finding.

(c) A petitioner may request in writing a review of a proposed finding within 30 calendar days of notification under paragraph (b) of this section. Petitioners must specify why the proposed finding should be reversed, based on the petition requirements and on

[3] An affidavit may be from a petitioner but HHS does not require that an affidavit be from a petitioner.

the information that the petitioners had already submitted. The request may not include any new information or documentation that was not included in the completed petition. If the petitioner obtains new information within this 30 day period, the petitioner should provide it to NIOSH. NIOSH will consider this new information as a revision of the petition under paragraph (a) of this section.

(d) Three HHS personnel, appointed by the Director of NIOSH, who were not involved in developing the proposed finding will complete reviews within 30 work days of the request for such a review. The Director of NIOSH will consider the results of the review and then make a final decision as to whether the petition satisfies the requirements for evaluation.

(e) Proposed findings established by NIOSH under paragraph (b) of this section will become final decisions in 31 calendar days if not reviewed under paragraph (d) of this section.

(f) Based on new information, NIOSH may, at its discretion, reconsider a decision not to select a petition for evaluation.

§ 83.12 How will NIOSH notify petitioners, the Board, and the public of petitions that have been selected for evaluation?

(a) NIOSH will notify the petitioner(s) in writing that it has selected the petition for evaluation. NIOSH will also provide the petitioner(s) with information on the steps of the evaluation and other processes required pursuant to these procedures.

(b) NIOSH will combine separate petitions and evaluate them as a single petition if, at this or at any point in the evaluation process under §§ 83.13 and 83.14, NIOSH finds such petitions represent the same class of employees.

(c) NIOSH will present petitions selected for evaluation to the Board with plans specific to evaluating each petition. Each evaluation plan will include the following elements:

(1) An initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation conducted under § 83.13 or § 83.14; and

(2) A list of activities for evaluating the radiation exposure potential of the class and the adequacy of existing records and information needed to conduct dose reconstructions for all class members under 42 CFR part 82.

(d) NIOSH may initiate work to evaluate a petition immediately, prior to presenting the petition and evaluation plan to the Board.

(e) NIOSH will publish a notice in the FEDERAL REGISTER notifying the public of its decision to evaluate a petition.

§ 83.13 How will NIOSH evaluate petitions, other than petitions by claimants covered under § 83.14?

(a) NIOSH will collect information on the types and levels of radiation exposures that potential members of the class may have incurred, as specified under 42 CFR 83.14, from the following potential sources, as necessary:

(1) The petition or petitions submitted on behalf of the class;

(2) DOE and AWE facility records and information;

(3) Potential members of the class and their survivors;

(4) Labor organizations who represent or represented employees at the facility during the relevant period of employment;

(5) Managers, radiation safety officials, and other witnesses present during the relevant period of employment at the DOE facility or AWE facility;

(6) NIOSH records from epidemiological research on DOE populations and records from dose reconstructions conducted under 42 CFR part 82;

(7) Records from research, dose reconstructions, medical screening programs, and other related activities conducted to evaluate the health and/or radiation exposures of DOE employees, DOE contractor or subcontractor employees, and/or AWE employees; and

(8) Other sources.

(b) The Director of OCAS may determine that records and/or information requested from DOE, an AWE, or another source to evaluate a petition is not, or will not be, available on a timely basis. Such a determination will be treated, for the purposes of the petition evaluation, as equivalent to a finding that the records and/or information requested are not available.

(1) Before the Director of OCAS makes such a determination, the

source(s) potentially in possession of such records and/or information will be allowed a reasonable amount of time, as determined by the Director of OCAS, to provide the records and/or information.

(2) Such a determination may take into account the types and quantity of records and/or information requested from the source, as well as any other factors that might be relevant to the judgment under paragraph (b)(1) of this this section of the amount of time that is reasonable to provide the records and/or information, which would be decided on a case-by-case basis by the Director of OCAS.

(c) NIOSH will evaluate records and information collected to make the following determinations:

(1) *Is it feasible to estimate the level of radiation doses of individual members of the class with sufficient accuracy?* (i) Radiation doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose, for every type of cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any member of the class, or if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose. NIOSH must also determine that it has information regarding monitoring, source, source term, or process from the site where the employees worked to serve as the basis for a dose reconstruction. This basis requirement does not limit NIOSH to using only or primarily information from the site where the employee worked, but a dose reconstruction must, as a starting point, be based on some information from the site where the employee worked.

(ii) In many circumstances, to establish a positive finding under paragraph (c)(1)(i) of this section would require, at a minimum, that NIOSH have access to reliable information on the identity or set of possible identities and maximum quantity of each radionuclide (the radioactive source material) to which members of the class were potentially exposed without adequate protection. Alternatively, if members of the class were potentially exposed without adequate protection to unmonitored radiation from radiation generating equipment (*e.g.*, particle accelerator, industrial x-ray equipment), in many circumstances, NIOSH would require relevant equipment design and performance specifications or information on maximum emissions.

(iii) In many circumstances, to establish a positive finding under paragraph (c)(1)(i) of this section would also require information describing the process through which the radiation exposures of concern may have occurred and the physical environment in which the exposures may have occurred.

(iv) In many circumstances, access to personal dosimetry data and area monitoring data is not necessary to estimate the maximum radiation doses that could have been incurred by any member of the class, although radiation doses can be estimated more precisely with such data.

(2) *How should the class be defined, consistent with the findings of the analysis discussed under paragraph (c)(1) of this section?* NIOSH will define the following characteristics of a class, taking into account the class definition proposed by the petition and modified as necessary to reflect the results of the evaluation under paragraph (c)(1) of this section:

(i) Any of the following employment parameters, as necessary to identify members included in the class: facility, job titles, duties, and/or specific work locations at the facility, the relevant time period, and any additional identifying characteristics of employment; and

(ii) If applicable, the identification of an exposure incident, when unmonitored radiation exposure during such an incident comprises the basis of the petition or the class definition.

(3) *Is there a reasonable likelihood that such radiation dose may have endangered the health of members of the class?* If it is not feasible to estimate with sufficient accuracy radiation doses for members of the class, as provided under paragraph (c)(1) of this section, then NIOSH must determine, as required by the statute, that "*there is a reasonable likelihood that such radiation dose may have*

endangered the health of members of the class" (42 U.S.C. 7384q(b)(2)).

(i) For classes of employees that may have been exposed to radiation during discrete incidents likely to have involved exceptionally high level exposures, such as nuclear criticality incidents or other events involving similarly high levels of exposures resulting from the failure of radiation protection controls, NIOSH will assume for the purposes of this section that any duration of unprotected exposure could cause a specified cancer, and hence may have endangered the health of members of the class. Presence with potential exposure during the discrete incident, rather than a quantified duration of potential exposure, will satisfy the health endangerment criterion.

(ii) For health endangerment not established on the basis of a discrete incident, as described under paragraph (c)(3)(i) of this section, NIOSH will specify a minimum duration of employment to satisfy the health endangerment criterion as having been employed for a number of work days aggregating at least 250 work days within the parameters established for the class or in combination with work days within the parameters established for one or more other classes of employees in the Cohort.

(d) NIOSH will submit a report of its evaluation findings to the Board and to the petitioner(s). The report will include the following elements:

(1) An identification of the relevant petitions;

(2) A proposed definition of the class or classes of employees to which the evaluation applies, and a summary of the basis for this definition, including, as necessary:

(i) Any justification that may be needed for the inclusion of groups of employees who were not specified in the original petition(s);

(ii) The identification of any groups of employees who were identified in the original petition(s) who should constitute a separate class of employees; or

(iii) The merging of multiple petitions that represent a single class of employees;

(3) The proposed class definition will address the following employment parameters:

(i) The DOE facility or the AWE facility that employed the class;

(ii) The job titles and/or job duties and/or work locations of class members;

(iii) The period of employment within which a class member must have been employed at the facility under the job titles and/or performing the job duties and/or working in the locations specified in this class definition;

(iv) If applicable, identification of an exposure incident, when potential radiation exposure during such an incident comprises the basis of the class definition;

(v) If necessary, any other parameters that serve to define the membership of the class; and

(vi) For a class for which it is not feasible to estimate radiation doses with sufficient accuracy, a minimum duration of employment within the parameters of the class for inclusion in the class, as defined under paragraph (c)(3) of this section;

(4) A summary of the findings concerning the adequacy of existing records and information for reconstructing doses for individual members of the class under the methods of 42 CFR part 82, and a description of the evaluation methods and information upon which these findings are based; and

(5) For a class for which it is not feasible to estimate radiation doses with sufficient accuracy, a summary of the basis for establishing the duration of employment requirement with respect to health endangerment.

§ 83.14 How will NIOSH evaluate a petition by a claimant whose dose reconstruction NIOSH could not complete under 42 CFR part 82?

(a) NIOSH may establish two classes for evaluation, to permit the timely adjudication of the existing cancer claim:

(1) A class of employees defined using the research and analyses already completed in attempting the dose reconstruction for the employee identified in the claimant's petition; and

(2) A class of co-workers similar to the class defined under paragraph (a)(1)

of this section, to be defined by NIOSH on the basis of further research and analyses, using the procedures under § 83.13.

(b) NIOSH will determine the health endangerment criteria for adding the class under paragraph (a)(1) of this section to the Cohort, using the procedures under § 83.13. NIOSH will report to the Board and to petitioner(s) the results of this determination, together with its finding under 42 CFR part 82 that there was insufficient information to complete the dose reconstruction. HHS will consider this finding under 42 CFR part 82 sufficient, without further consideration, to determine that it is not feasible to estimate the levels of radiation doses of individual members of the class with sufficient accuracy.

(c) NIOSH will evaluate the petition as it may concern a class of co-workers, as described under paragraph (a)(2) of this section, according to the procedures under § 83.13.

§ 83.15 How will the Board consider and advise the Secretary on a petition?

(a) NIOSH will publish a notice in the FEDERAL REGISTER providing notice of a Board meeting at which a petition will be considered, and summarizing the petition to be considered by the Board at the meeting and the findings of NIOSH from evaluating the petition.

(b) The Board will consider the petition and the NIOSH evaluation report at the meeting, to which the petitioner(s) will be invited to present views and information on the petition and the NIOSH evaluation findings. In considering the petition, both NIOSH and the members of the Board will take all steps necessary to prevent the disclosure of information of a personal nature, concerning the petitioners or others, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

(c) In considering the petition, the Board may obtain and consider additional information not addressed in the petition or the initial NIOSH evaluation report.

(d) NIOSH may decide to further evaluate a petition, upon the request of the Board. If NIOSH conducts further evaluation, it will report new findings to the Board and the petitioner(s).

(e) Upon the completion of NIOSH evaluations and deliberations of the Board concerning a petition, the Board will develop and transmit to the Secretary a report containing its recommendations. The Board's report will include the following:

(1) The identification and inclusion of the relevant petition(s);

(2) The definition of the class of employees covered by the recommendation;

(3) A recommendation as to whether or not the Secretary should designate the class as an addition to the Cohort;

(4) The relevant criteria under § 83.13(c) and findings and information upon which the recommendation is based, including NIOSH evaluation reports, information provided by the petitioners, any other information considered by the Board, and the deliberations of the Board.

§ 83.16 How will the Secretary decide the outcome(s) of a petition?

(a) The Director of NIOSH will propose, and transmit to all affected petitioners, a decision to add or deny adding classes of employees to the Cohort, including an iteration of the relevant criteria, as specified under § 83.13(c), and a summary of the information and findings on which the proposed decision is based. This proposed decision will take into consideration the evaluations of NIOSH and the report and recommendations of the Board, and may also take into consideration information presented or submitted to the Board and the deliberations of the Board. In the case of a petition that NIOSH has determined encompasses more than one class of employees, the Director of NIOSH will issue a separate proposed decision for each separate class of employees.

(b) HHS will only allow the petitioner(s) to contest a proposed decision to deny adding a class to the Cohort or to contest a health endangerment determination under § 83.13(c)(3)(ii). Such challenges must be submitted in writing within 30 calendar days and must include evidence that the proposed decision relies on a record of either substantial factual errors or substantial

errors in the implementation of the procedures of this part. Challenges may not introduce new information or documentation concerning the petition or the NIOSH or Board evaluation(s) that was not submitted or presented by the petitioner(s) or others to NIOSH or to the Board prior to the Board's issuing its recommendations under §83.15.

(c) A panel of three HHS personnel, independent of NIOSH and appointed by the Secretary, will conduct an administrative review based on a challenge submitted under paragraph (b) of this section and provide recommendations of the panel to the Secretary concerning its merits and the resolution of issues contested by the challenge. Reviews by the panel will consider, in addition to the views and information submitted by the petitioner(s) in the challenge, the proposed decision, the NIOSH evaluation report(s), and the report containing the recommendations of the Board issued prior to the proposed decision under §83.15. The reviews may also consider information presented or submitted to the Board and the deliberations of the Board prior to the issuance of the recommendations of the Board under §83.15. The panel shall consider whether HHS substantially complied with the procedures of this part, the factual accuracy of the information supporting the proposed decision, and the principal findings and recommendations of NIOSH and those of the Board issued under §83.15.

(d) The Secretary will make the final decision to add or deny adding a class to the Cohort, including the definition of the class, after considering information and recommendations provided to the Secretary by NIOSH, the Board, and from an HHS administrative review when such a review is conducted under paragraph (c) of this section. HHS will transmit a report of the decision to the petitioner(s), including an iteration of the relevant criteria, as specified under §83.13(c), and a summary of the information and findings on which the decision is based. HHS will also publish a notice summarizing the decision in the FEDERAL REGISTER.

§83.17 How will the Secretary report a final decision to add a class of employees to the Cohort and any action of Congress concerning the effect of the final decision?

(a) If the Secretary designates a class of employees to be added to the Cohort, the Secretary will transmit to Congress a report providing the designation, the definition of the class of employees covered by the designation, and the criteria and findings upon which the designation was based.[4]

(b) A designation of the Secretary will take effect 180 calendar days after the date on which the report of the Secretary is submitted to Congress, unless Congress takes an action that reverses or expedites the designation.

(c) After either the expiration of the congressional review period or notification of final congressional action, whichever comes first, the Secretary will transmit to DOL and to the petitioner(s) a report providing the definition of the class and one of the following outcomes:

(1) The addition of the class to the Cohort; or

(2) The result of any action by Congress to reverse or expedite the decision of the Secretary to add the class to the Cohort.

(d) The report specified under paragraph (c) of this section will be published on the Internet at *www.cdc.gov/niosh/ocas* and in the FEDERAL REGISTER.

§83.18 How can the Secretary cancel or modify a final decision to add a class of employees to the Cohort?

(a) The Secretary can cancel a final decision to add a class to the Cohort, or can modify a final decision to reduce the scope of a class added by the Secretary, if HHS obtains records relevant to radiation exposures of members of the class that enable NIOSH to estimate the radiation doses incurred by individual members of the class through dose reconstructions conducted under the requirements of 42 CFR part 82.

(b) Before canceling a final decision to add a class or modifying a final decision to reduce the scope of a class, the

[4] See 42 U.S.C. 7384l(14)(C)(ii).

Secretary intends to follow evaluation procedures that are substantially similar to those described in this part for adding a class of employees to the Cohort. The procedures will include the following:

(1) Publication of a notice in the FEDERAL REGISTER informing the public of the intent of the Secretary to review the final decision on the basis of new information and describing procedures for this review;

(2) An analysis by NIOSH of the utility of the new information for conducting dose reconstructions under 42 CFR part 82; the analysis will be performed consistently with the requirements for analysis of a petition by NIOSH under §§83.13(c)(1) and (2), and 83.13(c)(2) and (3);

(3) A recommendation by the Board to the Secretary as to whether or not the Secretary should cancel or modify his final decision that added the class to the Cohort, based upon a review by the Board of the NIOSH analysis under paragraph (b)(2) of this section and any other relevant information considered by the Board;

(4) An opportunity for members of the class to contest a proposed decision to cancel or modify the prior final decision that added the class to the Cohort, including a reasonable and timely effort by the Secretary to notify members of the class of this opportunity; and

(5) Publication in the FEDERAL REGISTER of a final decision to cancel or modify the prior final decision that added the class to the Cohort.

PART 84—APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

Subpart A—General Provisions

Subpart B—Application for Approval

Subpart C—Fees

Subpart D—Approval and Disapproval

Subpart E—Quality Control

Subpart F—Classification of Approved Respirators; Scope of Approval; Atmospheric Hazards; Service Time

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Subpart J—Supplied-Air Respirators

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Subpart L—Chemical Cartridge Respirators

Subpart M [Reserved]

Subpart N—Special Use Respirators

Subparts O–JJ [Reserved]

Subpart KK—Dust, Fume, and Mist; Pesticide; Paint Spray; Powered Air-Purifying High Efficiency Respirators and Combination Gas Masks

TABLES TO SUBPART KK OF PART 84

AUTHORITY: 29 U.S.C. 577a, 651 *et seq.*, and 657(g); 30 U.S.C. 3, 5, 7, 811, 842(h), 844.

SOURCE: 60 FR 30355, June 8, 1995, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 84 appear at 69 FR 18803, Apr. 9, 2004.

Subpart A—General Provisions

§ 84.1 Purpose.

The purpose of the regulations contained in this part 84 is:

(a) To establish procedures and prescribe requirements which must be met in filing applications for approval by

the National Institute for Occupational Safety and Health of respirators or changes or modifications of approved respirators;

(b) To establish a schedule of fees to be charged each applicant for the inspections, examinations, and testing conducted by the Institute under the provisions of this part;

(c) To provide for the issuance of certificates of approval or modifications of certificates of approval for respirators which have met the applicable construction, performance, and respiratory protection requirements set forth in this part; and

(d) To specify minimum requirements and to prescribe methods to be employed by the Institute and by the applicant in conducting inspections, examinations, and tests to determine the effectiveness of respirators used during entry into or escape from hazardous atmospheres.

§84.2 Definitions.

As used in this part—

(a) *Applicant* means an individual, partnership, company, corporation, association, or other organization that designs, manufactures, assembles, or controls the assembly of a respirator and who seeks to obtain a certificate of approval for such respirator.

(b) *Approval* means a certificate or formal document issued by the Institute stating that an individual respirator or combination of respirators has met the minimum requirements of this part, and that the applicant is authorized to use and attach an approval label to any respirator, respirator container, or instruction card for any respirator manufactured or assembled in conformance with the plans and specifications upon which the approval was based, as evidence of such approval.

(c) *Approved* means conforming to the minimum requirements of this part.

(d) *Auxiliary equipment* means a self-contained breathing apparatus, the use of which is limited in underground mine rescue and recovery operations to situations where the wearer has ready access to fresh air and at least one crew equipped with approved self-contained breathing apparatus of 2 hours or longer rating, is in reserve at a fresh-air base.

(e) *Certification and Quality Assurance Branch* means the Certification and Quality Assurance Branch, Division of Safety Research, Appalachian Laboratory for Occupational Safety and Health, National Institute for Occupational Safety and Health, 1095 Willowdale Road, Morgantown, West Virginia 26505–2888.

(f) *Compressed-breathing gas* means oxygen or air stored in a compressed state and supplied to the wearer in gaseous form.

(g) *dBA* means sound pressure levels in decibels, as measured with the A-weighted network of a standard sound level meter using slow response.

(h) *Dust* means a solid mechanically produced particle with a size ranging from submicroscopic to macroscopic.

(i) *Respirators for entry into and escape from* means respiratory devices providing protection during entry into and escape from hazardous atmospheres.

(j) *Respirators for escape only* means respiratory devices providing protection only during escape from hazardous atmospheres.

(k) A *facepiece* or *mouthpiece* is a respirator component designed to provide a gas-tight or dust-tight fit with the face and may include headbands, valves, and connections for canisters, cartridges, filters, or respirable gas source.

(l) *Final inspection* means that activity carried out on a product after all manufacturing and assembly operations are completed to insure completeness and adherence to performance or other specifications, including satisfactory appearance.

(m) *Fume* means a solid condensation particle, generally less than 1 micrometer in diameter.

(n) *Gas* means an aeriform fluid which is in a gaseous state at ordinary temperature and pressure.

(o) *Hazardous atmosphere* means:

(1) Any atmosphere containing a toxic or disease producing gas, vapor, dust, fume, mist, or pesticide, either immediately or not immediately dangerous to life or health; or

(2) Any oxygen-deficient atmosphere.

(p) A *hood* or *helmet* is a respirator component which covers the wearer's head and neck, or head, neck, and

shoulders, and is supplied with incoming respirable air for the wearer to breathe. It may include a headharness and connection for a breathing tube.

(q) *Immediately dangerous to life or health* means conditions that pose an immediate threat to life or health or conditions that pose an immediate threat of severe exposure to contaminants, such as radioactive materials, which are likely to have adverse cumulative or delayed effects on health.

(r) *Incoming inspection* means the activity of receiving, examining, and accepting only those materials and parts whose quality conforms to specification requirements.

(s) *In-process inspection* means the control of products at the source of production and at each step of the manufacturing process, so that departures from specifications can be corrected before defective components or materials are assembled into the finished product.

(t) *Institute* means the National Institute for Occupational Safety and Health, Department of Health and Human Services.

(u) *Liquefied-breathing gas* means oxygen or air stored in liquid form and supplied to the wearer in a gaseous form.

(v) *Mist* means a liquid condensation particle with a size ranging from submicroscopic to macroscopic.

(w) *MSHA* means the Mine Safety and Health Administration, U.S. Department of Labor.

(x) *Not immediately dangerous to life or health* means any hazardous atmosphere which may produce physical discomfort immediately, chronic poisoning after repeated exposure, or acute adverse physiological symptoms after prolonged exposure.

(y) *Oxygen-deficient atmosphere* means an atmosphere which contains an oxygen partial pressure of less than 148 millimeters of mercury (19.5 percent by volume at sea level).

(z) *Powered air-purifying respirator* means a device equipped with a facepiece, hood, or helmet, breathing tube, canister, cartridge, filter, canister with filter, or cartridge with filter, and a blower.

(aa) *Respirator* means any device designed to provide the wearer with respiratory protection against inhalation of a hazardous atmosphere.

(bb) *Single-use respirator* means a respirator that is entirely discarded after excessive resistance, sorbent exhaustion, or physical damage renders it unsuitable for further use.

(cc) *Vapor* means the gaseous state of a substance that is solid or liquid at ordinary temperature and pressure.

§ 84.3 Respirators for mine rescue or other emergency use in mines.

(a)(1) NIOSH and the Mine Safety and Health Administration (MSHA), U.S. Department of Labor, shall jointly review and issue certifications for respirators used for mine emergencies and mine rescue, including any associated service-life plans, users' manuals and other supporting documentation.

(2) Each certification for a respirator designed for mine rescue or other emergency use in mines shall include, as a condition of approval, any use limitations related to mine safety and health.

(b) NIOSH and MSHA shall jointly determine appropriate recall and retrofit remedies for field complaints or identified deficiencies involving any respirators used in the mining environment.

Subpart B—Application for Approval

§ 84.10 Application procedures.

(a) Inspection, examination, and testing leading to the approval of the types of respirators classified in subpart F of this part shall be undertaken by the Institute only pursuant to written applications which meet the minimum requirements set forth in this subpart B.

(b) Applications shall be submitted to the Certification and Quality Assurance Branch, and shall be accompanied by a check, bank draft, or money order in the amount specified in subpart C of this part, payable to the order of the National Institute for Occupational Safety and Health.

(c) Except as provided in §84.64, the examination, inspection, and testing of all respirators shall be conducted by the Certification and Quality Assurance Branch.

(d) Applicants, manufacturers, or their representatives may visit or communicate with the Certification and Quality Assurance Branch in order to discuss the requirements for approval of any respirator or the proposed designs thereof. No charge shall be made for such consultation and no written report shall be issued to applicants, manufacturers, or their representatives by the Institute as a result of such consultation.

(e) Respirators having electrical or electronic components that are required to be permissible under chapter I of title 30 shall be tested in accordance with 30 CFR part 18. Applications for approval of such respirators by MSHA shall be submitted in writing to: MSHA, Approval and Certification Center, Box 251, Industrial Park Road, Triadelphia, West Virginia 26059.

§ 84.11 Contents of application.

(a) Each application for approval shall contain a complete written description of the respirator for which approval is requested together with drawings and specifications (and lists thereof) showing full details of construction of the respirator and of the materials used.

(b) Drawings shall be titled, numbered, and dated; any revision dates shall be shown on the drawings, and the purpose of each revision being sought shall be shown on the drawing or described on an attachment to the drawing to which it applies.

(c) Each application for approval shall contain a proposed plan for quality control which meets the minimum requirements set forth in subpart E of this part.

(d) Each application shall contain a statement that the respirator has been pretested by the applicant as prescribed in § 84.64, and shall include the results of such tests.

(e) Each application for approval shall contain a statement that the respirator and component parts submitted for approval are either prototypes, or made on regular production tooling, with no operation included which will not be incorporated in regular production processing.

(The information collections contained in this section are approved under OMB control number 0920–0109)

§ 84.12 Delivery of respirators and components by applicant; requirements.

(a) Each applicant shall, when an application is filed pursuant to § 84.10, be advised by the Institute of the total number of respirators and component parts required for testing.

(b) The applicant shall deliver, at his own expense, the number of completely assembled respirators and component parts required for testing, to the Certification and Quality Assurance Branch.

(c) Respirators and component parts submitted for approval must be made from materials specified in the application.

(d) One completely assembled respirator approved under the provisions of this part may be retained by the Institute as a laboratory exhibit, the remaining respirators may be returned to the applicant at his own expense, upon written request within 30 days after notice of approval. If no such request is made, the respirators will be disposed of by the Institute in such manner as it deems appropriate.

(e) Where a respirator fails to meet the requirements for approval set forth in this part, all respirators and components delivered in accordance with this section may be returned to the applicant at his own expense, upon written request within 30 days after notice of disapproval. If no such request is made, the respirators will be disposed of by the Institute in such manner as it deems appropriate.

Subpart C—Fees

§ 84.20 Examination, inspection, and testing of complete respirator assemblies; fees.

Except as provided in § 84.22, the following fees shall be charged by the Institute for the examination, inspection and testing of complete respirator assemblies:

Self-contained breathing apparatus:	
Entry and escape, 1 hour or more ...	$3,500

Entry and escape, less than 1 hour	2,750
Escape only	2,000
Gas masks:	
Single hazard	1,100
Type N	4,100
Supplied-air respirators	750
Particulate respirators	1,250
Chemical cartridge respirators	1,150

§ 84.21 Examination, inspection, and testing of respirator components or subassemblies; fees.

Except as provided in § 84.22, the following fees shall be charged by the Institute for the examination, inspection and testing of the individual respirator components or subassemblies:

Facepieces	$450
Canisters	900
Cartridges	600
Filters	650
Hoses	250
Blowers	250
Harnesses	100

§ 84.22 Unlisted fees; additional fees; payment by applicant prior to approval.

(a) Applications for the examination, inspection and testing of complete respirator assemblies which are not listed in § 84.20, or for the examination, inspection, and testing of respirator components or subassemblies which are not listed in § 84.21, shall be accompanied by the following deposits:

Complete respirator assembly	$1,500
Each individual component or subassembly	500

(b) The Institute reserves the right to conduct any examination, inspection, or test it deems necessary to determine the quality and effectiveness of any listed or unlisted respirator assembly or respirator component or subassembly, and to assess the cost of such examinations, inspections, or tests against the applicant prior to the issuance of any approval for such assembly, component, or subassembly.

(c) The fees charged for the examination, inspection, and testing of unlisted respirator assemblies, unlisted individual respirator components or subassemblies, and for the additional examination, inspection, and testing of listed respirator assemblies and components or subassemblies shall be at the rate of $100 per day for each man-day required to be expended by the Institute.

(d) Upon completion of all examinations, inspections, and tests of unlisted respirator assemblies or components, or following the completion of any additional examination, inspections, or tests of listed assemblies, or components or subassemblies, including retesting subsequent to disapproval, the Institute shall advise the applicant in writing of the total cost assessed and the additional amount, if any, which must be paid to the Institute as a condition of approval.

(e) In the event the amount assessed by the Institute for unlisted assemblies, or components or subassemblies is less than the amount of the deposit submitted in accordance with paragraph (a) of this section, the Institute shall refund the overpayment upon the issuance of any approval or notice of disapproval.

Subpart D—Approval and Disapproval

§ 84.30 Certificates of approval; scope of approval.

(a) The Institute shall issue certificates of approval pursuant to the provisions of this subpart only for individual, completely assembled respirators which have been examined, inspected, and tested, and which meet the minimum requirements set forth in subparts H through L of this part, as applicable.

(b) The Institute will not issue certificates of approval for any respirator component or for any respirator subassembly.

(c) The Institute shall not issue an informal notification of approval. However, if the application for approval, submitted in accordance with § 84.11, states that the submitted respirator and component parts are only prototypes, the Institute will examine, inspect, and test such respirator and component parts in accordance with the provisions of this part. If, upon completion of such examinations, inspections and tests, it is found that the prototype meets the minimum requirements set forth in this part, the Institute may inform the applicant, in writing, of the results of the examinations, inspections, and tests, and may require

him to resubmit respirators and component parts made on regular production tooling, with no operations included which will not be incorporated in regular production processing, for further examination, inspection, and testing, prior to issuance of the certificate of approval.

(d) Applicants required to resubmit respirators and component parts made on regular production tooling, with no operation included which will not be incorporated in regular production processing, shall be charged fees in accordance with subpart C of this part.

§ 84.31 Certificates of approval; contents.

(a) The certificate of approval shall contain a classification and a description of the respirator or combination of respirators for which it is issued, as provided in this part.

(b) The certificate of approval shall specifically set forth any restrictions or limitations on the respirator's use in hazardous atmospheres.

(c) Each certificate of approval shall be accompanied by the drawings and specifications (and lists thereof) submitted by the applicant in accordance with § 84.11. These drawings and specifications shall be referenced in the certificate of approval, and shall be maintained by the applicant. The drawings and specifications listed in each certificate of approval shall set forth in detail the design and construction requirements which shall be met by the applicant during commercial production of the respirator.

(d) Each certificate of approval shall be accompanied by a reproduction of the approval label design to be employed by the applicant with each approved respirator, as provided in § 84.33.

(e) No test data or specific laboratory findings will accompany any certificate of approval, however, the Institute will release pertinent test data and specific findings upon written request by the applicant, or as required by statute or regulation.

(f) Each certificate of approval shall also contain the approved quality control plan as specified in § 84.42.

§ 84.32 Notice of disapproval.

(a) If, upon the completion of the examinations, inspections, and tests required to be conducted in accordance with the provisions of this part, it is found that the respirator does not meet the minimum requirements set forth in this part, the Institute shall issue a written notice of disapproval to the applicant.

(b) Each notice of disapproval shall be accompanied by all pertinent data or findings with respect to the defects of the respirator for which approval was sought with a view to the possible correction of any such defects.

(c) The Institute shall not disclose, except to the applicant or as required by statute or regulation, any data, findings, or other information with respect to any respirator for which a notice of disapproval is issued.

§ 84.33 Approval labels and markings; approval of contents; use.

(a) Full-scale reproductions of approval labels and markings, and a sketch or description of the method of application and position on the harness, container, canister, cartridge, filter, or other component, together with instructions for the use and maintenance of the respirator shall be submitted to the Institute for approval.

(b) Approval labels shall bear the emblem of the National Institute for Occupational Safety and Health and the seal of the Department of Health and Human Services, the applicant's name and address, an approval number assigned by the Institute and, where appropriate, restrictions or limitations placed upon the use of the respirator by the Institute. The approval number assigned by the Institute shall be designated by the prefix TC and a serial number.

(c) The Institute shall, where necessary, notify the applicant when additional labels, markings, or instructions will be required.

(d) Approval labels and markings shall only be used by the applicant to whom they were issued.

(e) Legible reproductions or abbreviated forms of the label approved by the Institute for use on each respirator shall be attached to or printed at the following locations:

Respirator type	Label type	Location
Self-contained breathing apparatus.	Entire	Harness assembly and canister (where applicable).
Gas mask	Entire	Mask container and canister.
Supplied air respirator	.....do	Respirator container or instruction card.
Particulate respirator	.....do	Respirator container and filter container.
	Abbreviated	Filters.
Chemical-cartridge respirator	Entire	Respirator container, cartridge container, and filter containers (where applicable).
	Abbreviated	Cartridges and filters and filter containers.

(f) The use of any Institute approval label obligates the applicant to whom it is issued to maintain or cause to be maintained the approved quality control sampling schedule and the acceptable quality level for each characteristic tested, and to assure that it is manufactured according to the drawings and specifications upon which the certificate of approval is based.

(g) Each respirator, respirator component, and respirator container shall, as required by the Institute to assure quality control and proper use of the respirator, be labeled distinctly to show the name of the applicant, and the name and letters or numbers by which the respirator or respirator component is designated for trade purposes, and the lot number, serial number, or approximate date of manufacture.

§ 84.34 Revocation of certificates of approval.

The Institute reserves the right to revoke, for cause, any certificate of approval issued pursuant to the provisions of this part. Such causes include, but are not limited to, misuse of approval labels and markings, misleading advertising, and failure to maintain or cause to be maintained the quality control requirements of the certificate of approval.

§ 84.35 Changes or modifications of approved respirators; issuance of modification of certificate of approval.

(a) Each applicant may, if he desires to change any feature of an approved respirator, request a modification of the original certificate of approval issued by the Institute for such respirator by filing an application for such modification in accordance with the provisions of this section.

(b) Applications shall be submitted as for an original certificate of approval, with a request for a modification of the existing certificate to cover any proposed change.

(c) The application shall be accompanied by appropriate drawings and specifications, and by a proposed quality control plan which meets the requirements of subpart E of this part.

(d) The application for modification, together with the accompanying material, shall be examined by the Institute to determine whether testing will be required.

(e) The Institute shall inform the applicant of the fee required for any additional testing and the applicant will be charged for the actual cost of any examination, inspection, or test required, and such fees shall be submitted in accordance with the provisions of subpart C of this part.

(f) If the proposed change or modification meets the requirements of this part, a formal certificate of modification will be issued, accompanied, where necessary, by a list of new and revised drawings and specifications covering the change(s) and reproductions of revised approval labels.

(The information collections contained in this section are approved under OMB control number 0920–0109)

§ 84.36 Delivery of changed or modified approved respirator.

An approved respirator for which a formal certificate of modification has been issued shall be delivered, with proper markings and containers, by the applicant to the Certification and Quality Assurance Branch, as soon as it is commercially produced.

Subpart E—Quality Control

§ 84.40 Quality control plans; filing requirements.

As a part of each application for approval or modification of approval submitted pursuant to this part, each applicant shall file with the Institute a proposed quality control plan which shall be designed to assure the quality of respiratory protection provided by the respirator for which approval is sought.

§ 84.41 Quality control plans; contents.

(a) Each quality control plan shall contain provisions for the management of quality, including:

(1) Requirements for the production of quality data and the use of quality control records;

(2) Control of engineering drawings, documentations, and changes;

(3) Control and calibration of measuring and test equipment;

(4) Control of purchased material to include incoming inspection;

(5) Lot identification, control of processes, manufacturing, fabrication, and assembly work conducted in the applicant's plant;

(6) Audit of final inspection of the completed product; and

(7) The organizational structure necessary to carry out these provisions.

(b) Each provision for incoming and final inspection in the quality control plan shall include a procedure for the selection of a sample of respirators and the components thereof for testing, in accordance with procedures set forth in Military Standard MIL–STD–414, 11 June 1957, including Change Notice No. 1, "Sampling Procedures and Tables for Inspection by Variables for Percent Defective," or an approved equivalent sampling procedure, or an approved combination of sampling procedures. The procedure of Military Standard MIL–STD–105D, 29 April 1963, "Sampling Procedures and Tables for Inspection by Attributes," is an example of an equivalent sampling procedure. MIL–STD–414 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from DODSSP, Standardization Document Order Desk, 700 Robbins Avenue, Bldg. 4D, Philadelphia, PA 19111–5094. Copies may be inspected at the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.* Copies of MIL–STD–105D may be inspected or obtained from the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888. Incoming bulk raw material inspection or verification of specification, and in-process inspection shall be sufficient to ensure control of product quality through the manufacturing cycle.

(c) The sampling procedure shall include a list of the characteristics to be tested by the applicant or his agent.

(d) The characteristics listed in accordance with paragraph (c) of this section shall be classified according to the potential effect of such defect and grouped into the following classes:

(1) *Critical.* A defect that judgment and experience indicate is likely to result in a condition immediately hazardous to life or health for individuals using or depending upon the respirator;

(2) *Major A.* A defect, other than critical, that is likely to result in failure to the degree that the respirator does not provide any respiratory protection, or a defect that reduces protection and is not detectable by the user;

(3) *Major B.* A defect, other than Major A or critical, that is likely to result in reduced respiratory protection, and is detectable by the user; and

(4) *Minor.* A defect that is not likely to materially reduce the usability of the respirator for its intended purpose, or a defect that is a departure from established standards and has little bearing on the effective use or operation of the respirator.

(e) The quality control inspection test method to be used by the applicant or his agent for each characteristic required to be tested shall be described in detail.

(f) Each item manufactured shall be 100 percent inspected for defects in all

critical characteristics and all defective items shall be rejected.

(g) The Acceptable Quality Level (AQL) for each major or minor defect so classified by the applicant shall be:

(1) *Major A.* 1.0 percent;

(2) *Major B.* 2.5 percent; and

(3) *Minor.* 4.0 percent.

(h) Except as provided in paragraph (i) of this section, inspection level IV as described in MIL–STD–414, 11 June 1957, including Change Notice No.1, "Sampling Procedures and Tables for Inspection by Variables for Percent Defective," or an equivalent procedure, shall be used for major and minor characteristics and 100 percent inspection for critical characteristics. Inspection level II as described in MIL–STD–105D, 29 April 1963, "Sampling Procedures and Tables for Inspection by Attributes," is an example of an equivalent procedure.

(i) Subject to the approval of the Institute, where the quality control plan provisions for raw material, processes, manufacturing, and fabrication, inspections are adequate to ensure control of finished article quality, destructive testing of finished articles may be conducted at a lower level of inspection than that specified in paragraph (h) of this section.

(The information collections contained in this section are approved under OMB control number 0920–0109)

§ 84.42 Proposed quality control plans; approval by the Institute.

(a) Each proposed quality control plan submitted in accordance with this subpart shall be reviewed by the Institute to determine its effectiveness in ensuring the quality of respiratory protection provided by the respirator for which an approval is sought.

(b) If the Institute determines that the proposed quality control plan submitted by the applicant will not ensure adequate quality control, the Institute shall require the applicant to modify the procedures and testing requirements of the plan prior to approval of the plan and issuance of any certificate of approval.

(c) Approved quality control plans shall constitute a part of and be incorporated into any certificate of approval issued by the Institute, and compliance with such plans by the applicant shall be a condition of approval.

§ 84.43 Quality control records; review by the Institute; revocation of approval.

(a) The applicant shall keep quality control inspection records sufficient to carry out the procedures required in MIL–STD–414, 11 June 1957, including Change Notice No. 1, "Sampling Procedures and Tables for Inspection by Variables for Percent Defective," or an approved equivalent sampling procedure. MIL–STD–105D, 29 April 1963, "Sampling Procedures and Tables for Inspection by Attributes," is an example of an approved equivalent sampling procedure. MIL–STD–414 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from DODSSP, Standardization Document Order Desk, 700 Robbins Avenue, Bldg. 4D, Philadelphia, Pa. 19111–5094. Copies may be inspected at the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.* Copies of MIL–STD–105D may be inspected or obtained from the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888.

(b) The Institute reserves the right to have its representatives inspect the applicant's quality control test methods, equipment, and records, and to interview any employee or agent of the applicant in regard to quality control test methods, equipment, and records.

(c) The Institute reserves the right to revoke, for cause, any certificate of approval where it is found that the applicant's quality control test methods,

equipment, or records do not ensure effective quality control over the respirator for which the approval was issued.

(The information collections contained in this section are approved under OMB control number 0920–0109)

Subpart F—Classification of Approved Respirators; Scope of Approval; Atmospheric Hazards; Service Time

§ 84.50 Types of respirators to be approved; scope of approval.

Approvals shall be issued for the types of respirators which have been classified pursuant to this subpart F, have been inspected, examined and tested by the Institute, in accordance with the provisions of subparts G through L of this part, and have been found to provide respiratory protection for fixed periods of time against the hazards specified in such approval.

§ 84.51 Entry and escape, or escape only; classification.

Respirators described in subparts H through L of this part shall be classified for use as follows:

(a) *Entry and escape.* Respirators designed and approved for use during entry into a hazardous atmosphere, and for escape from a hazardous atmosphere; or

(b) *Escape only.* Respirators designed and approved for use only during escape from a hazardous atmosphere.

§ 84.52 Respiratory hazards; classification.

Respirators described in subparts H through L of this part shall be classified as approved for use against any or all of the following respiratory hazards:

(a) Oxygen deficiency;

(b) Gases and vapors; and

(c) Particles, including dusts, fumes and mists.

§ 84.53 Service time; classification.

(a) Respirators described in subparts H through L of this part shall be classified, where applicable, as approved for use during the following prescribed service times:

(1) Four hours;

(2) Three hours;

(3) Two hours;

(4) One hour;

(5) Forty-five minutes;

(6) Thirty minutes;

(7) Fifteen minutes;

(8) Ten minutes;

(9) Five minutes; or

(10) Three minutes.

(b) Other service times may be prescribed by the Institute.

Subpart G—General Construction and Performance Requirements

§ 84.60 Construction and performance requirements; general.

(a) The Institute shall issue approvals for the types of respirators described in subparts H through L of this part which have met the minimum requirements set forth for such respirators in this part.

(b) In addition to the types of respirators specified in subparts H through L of this part, the Institute shall issue approvals for other respiratory protective devices not specifically described in this part subject to such additional requirements as may be imposed in accordance with § 84.63(c).

§ 84.61 General construction requirements.

(a) Respirators will not be accepted by the Institute for examination, inspection and testing unless they are designed on sound engineering and scientific principles, constructed of suitable materials and evidence good workmanship.

(b) Respirator components which come into contact with the wearer's skin shall be made of nonirritating materials.

(c) Components replaced during or after use shall be constructed of materials which will not be damaged by normal handling.

(d) Mouthpieces, hoods, helmets, and facepieces, except those employed in single-use respirators, shall be constructed of materials which will withstand repeated disinfection as recommended by the applicant in his instructions for use of the device.

§ 84.62 Component parts; minimum requirements.

(a) The component parts of each respirator shall be:

(1) Designed, constructed, and fitted to insure against creation of any hazard to the wearer;

(2) Assembled to permit easy access for inspection and repair of functional parts; and

(3) Assembled to permit easy access to parts which require periodic cleaning and disinfecting.

(b) Replacement parts shall be designed and constructed to permit easy installation and to maintain the effectiveness of the respirator.

§ 84.63 Test requirements; general.

(a) Each respirator and respirator component shall when tested by the applicant and by the Institute, and meet the applicable requirements set forth in subparts H through L of this part.

(b) Where a combination respirator is assembled from two or more types of respirators, as described in this part, each of the individual respirator types which have been combined shall, as applicable, meet the minimum requirements for such respirators set forth in subparts H through L of this part, and such combination respirators, except as specified in §84.70(b)(2), will be classified by the type of respirator in the combination which provides the least protection to the user.

(c) In addition to the minimum requirements set forth in subparts H through L of this part, the Institute reserves the right to require, as a further condition of approval, any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres.

(d) Where it is determined after receipt of an application that additional requirements will be required for approval, the Institute will notify the applicant in writing of these additional requirements, and necessary examinations, inspections, or tests, stating generally the reasons for such requirements, examinations, inspections, or tests.

§ 84.64 Pretesting by applicant; approval of test methods.

(a) Prior to making or filing any application for approval or modification of approval, the applicant shall conduct, or cause to be conducted, examinations, inspections, and tests of respirator performance which are equal to or exceed the severity of those prescribed in this part.

(b) With the application, the applicant shall provide a statement to the Institute showing the types and results of the examinations, inspections, and tests required under paragraph (a) of this section and state that the respirator meets the minimum requirements of subparts H through L of this part, as applicable. Complete examination, inspection, and test data shall be retained on file by the applicant and be submitted, upon request, to the Institute.

(c) The Institute may, upon written request by the applicant, provide drawings and descriptions of its test equipment and otherwise assist the applicant in establishing a test laboratory or securing the services of a testing agency.

(d) No approval will be issued until the Institute has validated the applicant's test results.

§ 84.65 Conduct of examinations, inspections, and tests by the Institute; assistance by applicant; observers; recorded data; public demonstrations.

(a) All examinations, inspections, and tests conducted pursuant to subparts H through L of this part will be under the sole direction and control of the Institute.

(b) The Institute may, as a condition of approval, require the assistance of the applicant or agents of the applicant during the assembly, disassembly, or preparation of any respirator or respirator component prior to testing or in the operation of such equipment during testing.

(c) Only Institute personnel, persons assisting the Institute pursuant to paragraph (b) of this section, and such other persons as are requested by the Institute or the applicant to be observers, shall be present during any examination, inspection, or test conducted

prior to the issuance of an approval by the Institute for the equipment under consideration.

(d) The Institute shall hold as confidential any analyses, drawings, specifications, or materials submitted by the applicant and shall not disclose any principles or patentable features of such equipment, except as required by statute or regulation.

(e) As a condition of each approval issued for any respirator, the Institute reserves the right, following the issuance of such approval, to conduct such public tests and demonstrations of the approved respiratory equipment as is deemed appropriate.

§ 84.66 Withdrawal of applications; refund of fees.

(a) Any applicant may, upon a written request submitted to the Institute, withdraw any application for approval of any respirator.

(b) Upon receipt of a written request for the withdrawal of an application, the Institute shall determine the total man-days expended and the amount due for services already performed during the course of any examinations, inspections, or tests conducted pursuant to such application. The total amount due shall be determined in accordance with the provisions of §84.22 and assessed against the fees submitted by the applicant. If the total amount assessed is less than the fees submitted, the Institute shall refund the balance together with a statement of the charges made for services rendered.

Subpart H—Self-Contained Breathing Apparatus

§ 84.70 Self-contained breathing apparatus; description.

(a) Self-contained breathing apparatus, including all completely assembled, portable, self-contained devices designed for use as respiratory protection during entry into and escape from or escape only from hazardous atmospheres, are described as follows:

(1) *Closed-circuit apparatus.* An apparatus of the type in which the exhalation is rebreathed by the wearer after the carbon dioxide has been effectively removed and a suitable oxygen concentration restored from sources composed of:

(i) Compressed oxygen; or

(ii) Chemical oxygen; or

(iii) Liquid-oxygen.

(2) Open-circuit apparatus. An apparatus of the following types from which exhalation is vented to the atmosphere and not rebreathed:

(i) *Demand-type apparatus.* An apparatus in which the pressure inside the facepiece in relation to the immediate environment is positive during exhalation and negative during inhalation; or

(ii) *Pressure-demand-type apparatus.* An apparatus in which the pressure inside the facepiece in relation to the immediate environment is positive during both inhalation and exhalation.

(b) The following respirators may be classified as designed and approved for use during emergency entry into a hazardous atmosphere:

(1) A combination respirator which includes a self-contained breathing apparatus; and

(2) A Type “C” or Type “CE” supplied air respirator, where—

(i) The self-contained breathing apparatus is classified for 3-, 5-, or 10-minute service time and the air line supply is used during entry; or

(ii) The self-contained breathing apparatus is classified for 15 minutes or longer service time and not more than 20 percent of the rated capacity of the air supply is used during entry.

(c) Self-contained breathing apparatus classified for less than 1 hour service time will not be approved for use during underground mine rescue and recovery operations except as auxiliary equipment.

(d) Self-contained breathing apparatus classified for less than 30 minutes’ service time will not be approved for use as auxiliary equipment during underground mine rescue and recovery operations.

§ 84.71 Self-contained breathing apparatus; required components.

(a) Each self-contained breathing apparatus described in §84.70 shall, where its design requires, contain the following component parts:

(1) Facepiece or mouthpiece, and noseclip;

(2) Respirable breathing gas container;
(3) Supply of respirable breathing gas;
(4) Gas pressure or liquid level gages;
(5) Timer;
(6) Remaining service life indicator or warning device;
(7) Hand-operated valves;
(8) Breathing bag;
(9) Safety relief valve or safety relief system; and
(10) Harness.
(b) The components of each self-contained breathing apparatus shall meet the minimum construction requirements set forth in subpart G of this part.

§ 84.72 Breathing tubes; minimum requirements.

Flexible breathing tubes used in conjunction with breathing apparatus shall be designed and constructed to prevent:
(a) Restriction of free head movement;
(b) Disturbance of the fit of facepieces and mouthpieces;
(c) Interference with the wearer's activities; and
(d) Shutoff of airflow due to kinking, or from chin or arm pressure.

§ 84.73 Harnesses; installation and construction; minimum requirements.

(a) Each apparatus shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the apparatus in position against the wearer's body.
(b) Harnesses shall be designed and constructed to permit easy removal and replacement of apparatus parts and, where applicable, provide for holding a full facepiece in the ready position when not in use.

§ 84.74 Apparatus containers; minimum requirements.

(a) Apparatus may be equipped with a substantial, durable container bearing markings which show the applicant's name, the type and commercial designation of the respirator it contains, and all appropriate approval labels.
(b) Containers supplied by the applicant for carrying or storing self-contained breathing apparatus will be inspected, examined, and tested as components of the respirator for which approval is sought.
(c) Containers for self-contained breathing apparatus shall be designed and constructed to permit easy removal of the apparatus.

§ 84.75 Half-mask facepieces, full facepieces, mouthpieces; fit; minimum requirements.

(a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes, either:
(1) By providing more than one facepiece size; or
(2) By providing one facepiece size which will fit varying facial shapes and sizes.
(b) Full facepieces shall provide for the optional use of corrective spectacles or lenses which shall not reduce the respiratory protective qualities of the apparatus.
(c) Apparatus with mouthpieces shall be equipped with noseclips which are securely attached to the mouthpiece or apparatus and provide an airtight seal.
(d) Facepieces shall be designed to prevent eyepiece, spectacle, and lens fogging.

§ 84.76 Facepieces; eyepieces; minimum requirements.

(a) Facepieces shall be designed and constructed to provide adequate vision which is not distorted by the eyepiece.
(b) All eyepieces shall be designed and constructed to be impact and penetration resistant. Federal Specification, Mask, Air Line: and Respirator, Air Filtering, Industrial, GGG–M–125d, October 11, 1965 with interim amendment-1, July 30, 1969, is an example of an appropriate standard for determining impact and penetration resistance. Copies of GGG–M–125d may be obtained from the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888.

§ 84.77 Inhalation and exhalation valves; minimum requirements.

(a) Inhalation and exhalation valves shall be provided where necessary and protected against damage and distortion.

(b) Exhalation valves shall be—

(1) Protected against external influence; and

(2) Designed and constructed to prevent inward leakage of contaminated air.

§ 84.78 Head harnesses; minimum requirements.

(a) Facepieces shall be equipped with adjustable and replaceable head harnesses designed and constructed to provide adequate tension during suspension and an even distribution of pressure over the entire area in contact with the face.

(b) Mouthpieces shall be equipped, where applicable, with adjustable and replaceable harnesses designed and constructed to hold the mouthpiece in place.

§ 84.79 Breathing gas; minimum requirements.

(a) Breathing gas used to supply apparatus shall be respirable and contain no less than 19.5 (dry atmosphere) volume percent of oxygen.

(b) Oxygen, including liquid oxygen, shall contain not less than 99.0 percent, by volume, of pure O_2, not more than 0.03%, by volume, carbon dioxide, and not more than 0.001%, by volume, carbon monoxide. Methods for making these determinations can be found in the U.S. Pharmacopeia National Formulary. Containers used for oxygen must not be treated with any toxic, sleep-inducing, narcosis-producing, or respiratory tract irritating compounds.

(c) Compressed, gaseous breathing air shall meet the applicable minimum grade requirements for Type I gaseous air set forth in the Compressed Gas Association Commodity Specification for Air, G–7.1, 1966 (Grade D or higher quality). G–7.1 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018. Copies may be inspected at the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(d) Compressed, liquefied breathing air shall meet the applicable minimum grade requirements for Type II liquid air set forth in the Compressed Gas Association Commodity Specification for Air, G–7.1, 1966 (Grade B or higher quality). G–7.1 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018. Copies may be inspected at the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

§ 84.80 Interchangeability of oxygen and air prohibited.

Approvals shall not be issued by the Institute for any apparatus, combination of respirator assemblies, or any apparatus or respirator component which is designed or constructed to permit the interchangeable use of oxygen and air.

§ 84.81 Compressed breathing gas and liquefied breathing gas containers; minimum requirements.

(a) Compressed breathing gas and liquefied breathing gas containers shall meet the minimum requirements of the Department of Transportation for interstate shipment of such containers when fully charged.

(b) Such containers shall be permanently and legibly marked to identify their contents, e.g., compressed breathing air, compressed breathing oxygen, liquefied breathing air, or liquefied breathing oxygen.

(c) Containers normally removed from apparatus for refilling shall be equipped with a dial indicating gage

which shows the pressure in the container.

(d) Compressed breathing gas contained valves or a separate charging system or adapter provided with each apparatus shall be equipped with outlet threads specified for the service by the American Standards Association, Compressed Gas Cylinder Valve Outlet and Inlet Connections, B57.1–1965. B57.1–1965 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American National Standards Institute, Inc., 1430 Broadway, New York, NY Copies may be inspected at the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

§ 84.82 Gas pressure gages; minimum requirements.

(a) Gas pressure gages employed on compressed breathing gas containers shall be calibrated in pounds per square inch.

(b) Liquid-level gages shall be calibrated in fractions of total container capacity, or in units of liquid volume.

(c) Gas pressure gages other than those specified in paragraphs (a) and (b) of this section shall be calibrated in:

(1) Pounds per square inch; or

(2) In fractions of total container capacity; or

(3) Both in pounds per square inch and fractions of total container capacity.

(d)(1) Dial-indicating gages shall be reliable to within ±5 percent of full scale when tested both up and down the scale at each of 5 equal intervals.

(2) The full-scale graduation of dial-indicating gages shall not exceed 150 percent of the maximum rated cylinder pressures specified for the container in applicable Department of Transportation specifications or permits.

(e)(1) Stem-type gages shall be readable by sight and by touch and shall have a stem travel distance of not less than one-fourth inch between each graduation.

(2) A minimum of five graduations shall be engraved on the stem of each gage and these graduations shall include readings for empty, one-quarter, one-half, three-quarters, and full.

(3) Stem gage readings shall not vary from true readings by more than one-sixteenth inch per inch of stem travel.

(f) The loss of gas through a broken gage or severed gage connection shall not exceed 70 liters per minute when the cylinder pressure is 6,900 $kN/m.^2$ (1,000 pounds per square inch gage) or when the liquid level is at one-half.

(g) Where gages are connected to the apparatus through a gage line, the gage and line shall be capable of being isolated from the apparatus except where the failure of the gage or line would not impair the performance or service life of the apparatus.

(h) Oxygen pressure gages shall have the words “Oxygen” and “Use No Oil” marked prominently on the gage.

(i)(1) Apparatus using compressed breathing gas, except apparatus classified for escape only, shall be equipped with gages visible to the wearer which indicate the remaining gas content in the container.

(2) Apparatus using liquefied breathing gas, except apparatus classified for escape only, shall be equipped with gages visible to the wearer which indicate the remaining liquid content in the container; however, where the liquid content cannot be rapidly vented, and the service time of the device begins immediately after filling, a timer shall be provided in place of a visible gage.

§ 84.83 Timers; elapsed time indicators; remaining service life indicators; minimum requirements.

(a) Elapsed time indicators shall be provided for apparatus with a chemical oxygen source, except:

(1) Apparatus used for escape only; or

(2) Liquefied breathing gas apparatus equipped with gages visible to the wearer which indicate the remaining liquid content in the container.

(b) The timer or other indicator shall be accurately calibrated in minutes of remaining service life.

(c) Timers shall be readable by sight and by touch during use by the wearer.

(d) Timers shall be equipped with automatically preset alarms which will warn the wearer for a period of 7 seconds or more after the preset time has elapsed.

(e) Remaining service-life indicators or warning devices shall be provided in addition to a pressure gage on compressed gas self-contained breathing apparatus, except apparatus used for escape only, and shall operate automatically without preadjustment by the wearer.

(f) Each remaining service-life indicator or warning device shall give an alarm when the remaining service life of the apparatus is reduced within a range of 20 to 25 percent of its rated service time.

§ 84.84 Hand-operated valves; minimum requirements.

(a) Hand-operated valves shall be designed and constructed to prevent removal of the stem from the valve body during normal usage to insure against a sudden release of the full pressure of the container when the valve is opened.

(b) Valves shall be designed or positioned to prevent accidental opening and closing, and damage from external forces.

(c) Valves operated during use of the apparatus shall be installed in locations where they can be readily adjusted by the wearer.

(d) Main-line valves, designed and constructed to conserve gas in the event of a regulator or demand valve failure, shall be provided in addition to gas container valves, except when such failure will not affect performance.

(e) Hand-operated bypass systems designed and constructed to permit the wearer to breathe and to conserve his gas supply in the event of a regulator or demand valve failure, shall be provided where necessary.

(f) Valves installed on apparatus shall be clearly distinguishable from one another by sight and touch.

(g) The bypass system valve control shall be colored red.

(h) A main-line or bypass valve or system will not be required on apparatus for escape only.

(i) Safety relief valves or systems, designed and constructed to release excess pressure in the breathing circuit, shall be provided on closed-circuit apparatus, and shall meet the following requirements:

(1) The relief valve or system shall operate automatically when the pressure in the breathing circuit on the inhalation side of the breathing bag reaches 13 mm. (one-half inch) water-column height of pressure above the minimum pressure required to fill the breathing bag, within the breathing resistance requirements for the apparatus.

(2) The relief valve or system shall be designed to prevent external atmospheres from entering the breathing circuit.

(3) The relief valve or system shall be designed to permit manual overriding for test purposes and in the event of a failure in the valve or system.

§ 84.85 Breathing bags; minimum requirements.

(a) Breathing bags shall have sufficient volume to prevent gas waste during exhalation and to provide an adequate reserve for inhalation.

(b) Breathing bags shall be constructed of materials which are flexible and resistant to gasoline vapors.

(c) Breathing bags shall be installed in a location which will protect them from damage or collapse by external forces, except on apparatus classified for escape only.

§ 84.86 Component parts exposed to oxygen pressures; minimum requirements.

Each applicant shall certify that the materials employed in the construction of component parts exposed to oxygen pressures above atmospheric pressure are safe and compatible for their intended use.

§ 84.87 Compressed gas filters; minimum requirements.

All self-contained breathing apparatus using compressed gas shall have a filter downstream of the gas source

to effectively remove particles from the gas stream.

§ 84.88 Breathing bag test.

(a) Breathing bags will be tested in an air atmosphere saturated with gasoline vapor at room temperature (24–30 °C./75–85 °F.) for a continuous period of twice the rated time of the apparatus (except for apparatus for escape only where the test period shall be the rated time of the apparatus).

(b) The bag will be operated during this test by a breathing machine with 24 respirations per minute and a minute-volume of 40 liters.

(c) A breathing machine cam with a work rate of 622 kp.-m./min. will be used. The dimensions of a suitable breathing machine cam are available from the Institute upon request.

(d) The air within the bag(s) shall not contain more than 100 parts per million of gasoline vapor at the end of the test.

§ 84.89 Weight requirement.

(a) The completely assembled and fully charged apparatus shall not weigh more than 16 kg. (35 pounds); however, where the weight decreases by more than 25 percent of its initial charge weight during its rated service life, the maximum allowable weight of a completely assembled and fully charged apparatus shall be 18 kg. (40 pounds).

(b) Where an apparatus employs equipment which contributes materially to the wearer's comfort, e.g., a cooling system, the completely assembled and fully charged apparatus shall not weigh more than 18 kg. (40 pounds) regardless of the decrease in weight during use.

§ 84.90 Breathing resistance test; inhalation.

(a) Resistance to inhalation airflow will be measured in the facepiece or mouthpiece while the apparatus is operated by a breathing machine as described in § 84.88.

(b) The inhalation resistance of open-circuit apparatus shall not exceed 32 mm. (1.25 inch) water-column height (at a flow rate of 120 liters per minute).

(c) The inhalation resistance of closed-circuit apparatus shall not exceed the difference between exhalation resistance (§ 84.91(e)) and 10 cm. (4 inches) water-column height.

§ 84.91 Breathing resistance test; exhalation.

(a) Resistance to exhalation airflow will be measured in the facepiece or mouthpiece of open-circuit apparatus with air flowing at a continuous rate of 85 liters per minute.

(b) The exhalation resistance of demand apparatus shall not exceed 25 mm. (1 inch) water-column height.

(c) The exhalation resistance of pressure-demand apparatus shall not exceed the static pressure in the facepiece by more than 51 mm. (2 inches) water-column height.

(d) The static pressure (at zero flow) in the facepiece shall not exceed 38 mm. (1.5 inches) water-column height.

(e) Resistance to exhalation airflow will be measured in the facepiece or mouthpiece of closed-circuit apparatus with a breathing machine as described in § 84.88, and the exhalation resistance shall not exceed 51 mm. (2 inches) water-column height.

§ 84.92 Exhalation valve leakage test.

(a) Dry exhalation valves and valve seats will be subjected to a suction of 25 mm. (1 inch) water-column height while in a normal operating position.

(b) Leakage between the valve and the valve seat shall not exceed 30 milliliters per minute.

§ 84.93 Gas flow test; open-circuit apparatus.

(a) A static-flow test will be performed on all open-circuit apparatus.

(b) The flow from the apparatus shall be greater than 200 liters per minute when the pressure in the facepiece of demand-apparatus is lowered by 51 mm. (2 inches) water-column height when full container pressure is applied.

(c) Where pressure demand apparatus are tested, the flow will be measured at zero gage pressure in the facepiece.

(d) Where apparatus with compressed-breathing-gas containers are tested, the flow test shall also be made with 3,450 $kN/m.^2$ (500 p.s.i.g.) container pressure applied.

§ 84.94 Gas flow test; closed-circuit apparatus.

(a) Where oxygen is supplied by a constant-flow device only, the rate of flow shall be at least 3 liters per minute for the entire rated service time of the apparatus.

(b) Where constant flow is used in conjunction with demand flow, the constant flow shall be greater than 1.5 liters per minute for the entire rated service time.

(c) All demand-flow devices shall provide at least 30 liters of oxygen per minute when in the fully open position.

§ 84.95 Service time test; open-circuit apparatus.

(a) Service time will be measured with a breathing machine as described in § 84.88.

(b) The open-circuit apparatus will be classified according to the length of time it supplies air or oxygen to the breathing machine.

(c) The service time obtained on this test will be used to classify the open-circuit apparatus in accordance with § 84.53.

§ 84.96 Service time test; closed-circuit apparatus.

(a) The closed-circuit apparatus will be classified according to the length of time it supplies adequate breathing gas to the wearer during man test No. 4 described in Table 4 of this subpart.

(b) The service time obtained on man test No. 4 will be used to classify the closed-circuit apparatus in accordance with § 84.53.

§ 84.97 Test for carbon dioxide in inspired gas; open- and closed-circuit apparatus; maximum allowable limits.

(a) *Open-circuit apparatus.* (1) The concentration of carbon dioxide in inspired gas in open-circuit apparatus will be measured at the mouth while the apparatus mounted on a dummy head is operated by a breathing machine. An acceptable method for measuring the concentration of carbon dioxide is described in Bureau of Mines Report of Investigations 6865, A Machine-Test Method for Measuring Carbon Dioxide in the Inspired Air of Self-Contained Breathing Apparatus, 1966. Copies of Report of Investigations 6865 may be inspected or obtained from the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV. 26505–2888.

(2) The breathing rate will be 14.5 respirations per minute with a minute-volume of 10.5 liters.

(3) A sedentary breathing machine cam will be used.

(4) The apparatus will be tested at a temperature of 27 ±2 °C. (80 ±5 °F.).

(5) A concentration of 5 percent carbon dioxide in air will be exhaled into the facepiece.

(b) *Closed-circuit apparatus.* The concentration of carbon dioxide in inspired gas in closed-circuit apparatus will be measured at the mouth while the parts of the apparatus contributing to dead-air space are mounted on a dummy head and operated by the breathing machine as in paragraphs (a) (1) through (5) of this section.

(c) During the testing required by paragraphs (a) and (b) of this section, the concentration of carbon dioxide in inspired gas at the mouth will be continuously recorded, and the maximum average concentration during the inhalation portion of the breathing cycle shall not exceed the following limits:

Where the service time is	Maximum allowable average concentration of carbon dioxide in inspired air percent by volume
Not more than 30 minutes	2.5
1 hour	2.0
2 hours	1.5
3 hours	1.0
4 hours	1.0

(d) In addition to the test requirements for closed-circuit apparatus set forth in paragraph (b) of this section, gas samples will be taken during the course of the man tests described in Tables 1, 2, 3, and 4 of this subpart. These gas samples will be taken from the closed-circuit apparatus at a point downstream of the carbon dioxide sorbent, and they shall not contain more than 0.5 percent carbon dioxide at any time, except on apparatus for escape only, using a mouthpiece only, the sample shall not contain more than 1.5 percent carbon dioxide at any time.

§ 84.98 Tests during low temperature operation.

(a) The applicant shall specify the minimum temperature for safe operation and two persons will perform the tests described in paragraphs (c) and (d) of this section, wearing the apparatus according to applicant's directions. At the specified temperature, the apparatus shall meet all the requirements described in paragraph (e) of this section.

(b) The apparatus will be precooled at the specified minimum temperature for 4 hours.

(c) The apparatus will be worn in the low temperature chamber for 30 minutes, or for the service time of the apparatus, whichever is less.

(d) During the test period, alternate 1-minute periods of exercise and rest will be required with the exercise periods consisting of stepping onto and off a box 21.5 cm. (8½ inches) high at a rate of 30 cycles per minute.

(e)(1) The apparatus shall function satisfactorily at the specified minimum temperature on duplicate tests.

(2) The wearer shall have sufficient unobscured vision to perform the work.

(3) The wearer shall not experience undue discomfort because of airflow restriction or other physical or chemical changes in the operation of the apparatus.

(f) Auxiliary low-temperature parts which are commercially available to the user may be used on the apparatus to meet the requirements described in paragraph (e) of this section.

§ 84.99 Man tests; testing conditions; general requirements.

(a) The man tests described in Tables 1, 2, 3, and 4 of this subpart represent the workload performed in the mining, mineral, or allied industries by a person wearing the apparatus tested.

(b) The apparatus tested will be worn by Institute personnel trained in the use of self-contained breathing apparatus, and the wearer will, before participating in these tests, pass a physical examination conducted by a qualified physician.

(c) All man tests will be conducted by the Institute.

(d) The apparatus will be examined before each man test to ensure that it is in proper working order.

(e) Breathing resistance will be measured within the facepiece or mouthpiece and the wearer's pulse and respiration rate will be recorded during each 2 minute sample period prescribed in tests 1, 2, 3, and 4.

(f) Man tests 1, 2, 3, 4, 5, and 6 will be conducted in duplicate.

(g) If man tests are not completed through no fault of the apparatus, the test will be repeated.

§ 84.100 Man tests 1, 2, 3, and 4; requirements.

Man tests 1, 2, 3, and 4, set forth in Tables 1, 2, 3, and 4 of this subpart, respectively, prescribe the duration and sequence of specific activities. These tests will be conducted to—

(a) Familiarize the wearer with the apparatus during use;

(b) Provide for a gradual increase in activity;

(c) Evaluate the apparatus under different types of work and physical orientation; and

(d) Provide information on the operating and breathing characteristics of the apparatus during actual use.

§ 84.101 Man test 5; requirements.

(a) Test 5 will be conducted to determine the maximum length of time the apparatus will supply the respiratory needs of the wearer while he is sitting at rest.

(b) The wearer will manipulate the devices controlling the supply of breathing gas to the advantage of the apparatus.

(c) Samples of inspiration from within the apparatus facepiece or mouthpiece shall be taken once every 15 minutes, and shall meet the minimum requirement for oxygen specified in §84.79(a), and the maximum allowable average concentration of carbon dioxide specified in §84.97(c).

(d) One sample of inspiration will be taken in the case of 3-, 5-, and 10-minute apparatus.

§ 84.102 Man test 6; requirements.

(a) Man test 6 will be conducted with respect to liquefied breathing gas apparatus only.

(b) This test will be conducted to evaluate operation of the apparatus in other than vertical positions.

(c) The wearer will lie face downward for one-fourth the service life of the apparatus with a full charge of liquefied breathing gas, and then a one-quarter full charge of liquefied breathing gas.

(d) The test will be repeated with the wearer lying on each side and on his back.

(e) The oxygen content of the gas supplied to the wearer by the apparatus will be continuously measured.

§ 84.103 Man tests; performance requirements.

(a) The apparatus shall satisfy the respiratory requirements of the wearer for the classified service time.

(b) Fogging of the eyepiece shall not obscure the wearer's vision, and the wearer shall not experience undue discomfort because of fit or other characteristics of the apparatus.

(c) When the ambient temperature during testing is 24±6 °C. (75±10 °F.), the maximum temperature of inspired air recorded during man tests shall not exceed the following, after correction for deviation from 24 °C. (75 °F.):

Where service life of apparatus is—	Where percent relative humidity of inspired air is—	Maximum permissible temperature of inspired air shall not exceed—	
		°F.	°C.
¼ hour or less	0–100	135	57
¼ hour to ¾ hour	0–50	125	52
	50–100	[1] 110	[1] 43
1 to 2 hours	0–50	115	46
	50–100	[1] 105	[1] 41
3 hours	0–50	110	43
	50–100	[1] 100	[1] 38
4 hours	0–50	105	41
	50–100	[1] 95	[1] 35

[1] Where percent relative humidity is 50–100 and apparatus is designed for escape only, these maximum permissible temperatures will be increased by 5 °C (10 °F).

§ 84.104 Gas tightness test; minimum requirements.

(a) Each apparatus will be tested for tightness by persons wearing it in an atmosphere of 1,000 p.p.m. isoamyl acetate.

(b) Six persons will each wear the apparatus in the test concentrations specified in paragraph (a) of this section for 2 minutes and none shall detect the odor or taste of the test vapor.

TABLES TO SUBPART H OF PART 84

TABLE 1—DURATION AND SEQUENCE OF SPECIFIC ACTIVITIES FOR TEST 1, IN MINUTES

[42 CFR part 84, subpart H]

Activity	Service time—							
	3 minutes	5 minutes	10 minutes	15 minutes	30 minutes	45 minutes	1 hour	2, 3, and 4 hours
Sampling and readings	.....	.....	.....	2	2	2	2	Perform 1 hour test 2, 3, or 4 times respectively.
Walks at 4.8 km. (3 miles) per hour.	3	5	3	4	8	12	18	
Sampling and readings	.....	.....	2	2	2	2	2	
Walks at 4.8 km. (3 miles) per hour.	.....	.....	3	5	8	12	18	
Sampling and readings	.....	.....	2	2	2	2	2	
Walks at 4.8 km. (3 miles) per hour.	.....	.....	.....	.....	6	13	16	
Sampling and readings	.....	.....	.....	.....	2	2	2	

TABLE 2—DURATION AND SEQUENCE OF SPECIFIC ACTIVITIES FOR TEST 2, IN MINUTES

[42 CFR part 84, subpart H]

Activity	Service time—							
	3 minutes	5 minutes	10 minutes	15 minutes	30 minutes	45 minutes	1 hour	2, 3 and 4 hours [1]
Sampling and readings	.....	.....	.....	2	2	2	2	2
Walks at 4.8 km. (3 miles) per hour	.....	.....	1	1	3	4	6	10.
Carries 23 kg. (50 pound) weight over overcast	.....	.....	1 time in 2 minutes	1 time in 2 minutes	2 times in 4 minutes	3 times in 6 minutes	4 times in 8 minutes	5 times in 10 minutes.
Walks at 4.8 km. (3 miles) per hour	.....	.....	.....	1	3	3	3	5.
Climbs vertical treadmill [2] (or equivalent)	1	1	1	1	1	1	1	1.
Walks at 4.8 km. (3 miles) per hour	.....	1	1	.....	.....	2	3	5
Climbs vertical treadmill (or equivalent)	.....	1	.....	.....	.....	1	1	1.
Sampling and readings	.....	.....	.....	.....	2	2	2	2.
Walks at 4.8 km. (3 miles) per hour	.....	.....	.....	2	2	3	5	11.
Climbs vertical treadmill (or equivalent)	.....	.....	.....	1	1	1	1	1.
Carries 23 kg. (50 pound) weight over overcast	.....	.....	.....	1 time in 2 minutes	3 times in 6 minutes	4 times in 8 minutes	5 times in 10 minutes	5 times in 10 minutes.
Sampling and readings	.....	.....	2	.....	.....	2	2	2.
Walks at 4.8 km. (3 miles) per hour	.....	.....	.....	1	3	3	3	.....
Climbs vertical treadmill (or equivalent)	.....	.....	1	1	1	1	1	Then repeat above activities once.
Walks at 4.8 km. (3 miles) per hour	.....	.....	2	.....	.....	2	3	
Climbs vertical treadmill (or equivalent)	.....	.....	.....	.....	.....	1	1	.....
Carries 20 kg. (45 pound) weight and walks at 4.8 km. (3 miles) per hour	1	.....	.....	.....	.....	.....	2	.....
Walks at 4.8 km. (3 miles) per hour	1	2	.....	.....	.....	1	4	.....
Sampling and readings	.....	.....	.....	2	2	2	2	.....

[1] Total test time for Test 2 for 2-hour, 3-hour, and 4-hour apparatus is 2 hours.
[2] Treadmill shall be inclined 15° from vertical and operated at a speed of 1 foot per second.

TABLE 3—DURATION AND SEQUENCE OF SPECIFIC ACTIVITIES FOR TEST 3, IN MINUTES

[42 CFR part 84, subpart H]

Activity	Service time—							
	3 minutes	5 minutes	10 minutes	15 minutes	30 minutes	45 minutes	1 hour	2, 3 and 4 hours [1]
Sampling and readings	.....	.....	.....	2	2	2	2	([2])
Walks at 4.8 km. (3 miles) per hour	.....	.....	1	1	2	2	3	.....
Runs at 9.7 km. (6 miles) per hour	1	1	1	1	1	1	1	.....
Pulls 20 kg. (45 pound) weight to 5 feet	.....	15 times in 1 minute	.....	30 times in 2 minutes	30 times in 2 minutes	30 times in 2 minutes	60 times in 6 minutes	.....
Lies on side	1/2	1	1	2	3	4	5	.....
Lies on back	1/2	1	1	2	2	3	3	.....
Crawls on hands and knees	1	1	1	2	2	2	2	.....
Sampling and readings	.....	.....	2	.....	2	2	2	.....
Runs at 9.7 km. (6 miles) per hour	.....	.....	.....	1	1	1	1	.....
Walks at 4.8 km. (3 miles) per hour	.....	.....	.....	.....	2	8	10	.....

TABLE 3—DURATION AND SEQUENCE OF SPECIFIC ACTIVITIES FOR TEST 3, IN MINUTES—Continued

[42 CFR part 84, subpart H]

Activity	Service time—							
	3 minutes	5 minutes	10 minutes	15 minutes	30 minutes	45 minutes	1 hour	2, 3 and 4 hours[1]
Pulls 20 kg. (45 pound) weight to 5 feet	.....	.....	30 times in 2 minutes	.....	60 times in 6 minutes	60 times in 6 minutes	60 times in 6 minutes	.....
Sampling and readings	.....	.....	.....	2	.....	2	2	.....
Walks at 4.8 km. (3 miles) per hour	.....	.....	1	.....	3	4	10	.....
Lies on side	.....	.....	.....	.....	.....	2	4	.....
Lies on back	.....	.....	.....	.....	.....	2	1	.....
Sampling and readings	.....	.....	.....	.....	2	2	2	.....

[1] Total test time for Test 3 for 2-hour, 3-hour, and 4-hour apparatus is 2 hours.
[2] Perform test No. 3 for 1 hr. apparatus; then perform test No. 1 for 1 hour apparatus.

TABLE 4—DURATION AND SEQUENCE OF SPECIFIC ACTIVITIES FOR TEST 4, IN MINUTES

[42 CFR part 84, subpart H]

Activity	Service time—									
	3 minutes	5 minutes	10 minutes	15 minutes	30 minutes	45 minutes	1 hour	2 hours	3 hours	4 hours
Sampling and readings	.....	.....	.....	2	2	2	2	(2)	(3)	(4)
Walks at 4.8 km. (3 miles) per hour	.....	.....	.....	1	2	2	2	.....	.....	.....
Climbs vertical treadmill[1] (or equivalent)	1	1	1	1	1	1	1	.....	.....	.....
Walks at 4.8 km. (3 miles) per hour	.....	1	1	1	2	2	2	.....	.....	.....
Pulls 20 kg. (45 pound) weight to 5 feet	.....	30 times in 2 minutes	30 times in 2 minutes	30 times in 2 minutes	60 times in 5 minutes	60 times in 5 minutes	60 times in 5 minutes	.....	.....	.....
Walks at 4.8 km. (3 miles) per hour	.....	.....	1	1	1	2	3	.....	.....	.....
Carries 23 kg. (50 pound) weight over overcast	.....	.....	.....	1 time in 1 minute	1 time in 1 minute	2 times in 3 minutes	4 times in 8 minutes	.....	.....	.....
Sampling and readings	.....	.....	2	.....	2	2	2	.....	.....	.....
Walks at 4.8 km. (3 miles) per hour	.....	.....	.....	1	3	3	4	.....	.....	.....
Runs at 9.7 km. (6 miles) per hour	.....	1	1	1	1	1	1	.....	.....	.....
Carries 23 kg. (50 pound) weight over overcast	.....	.....	1 time in 1 minute	1 time in 1 minute	2 times in 3 minutes	4 times in 6 minutes	6 times in 9 minutes	.....	.....	.....
Pulls 20 kg (45 pound) weight to 5 feet	15 times in 1 minute	.....	.....	15 times in 1 minute	60 times in 5 minutes	30 times in 2 minutes	36 times in 3 minutes	.....	.....	.....
Sampling and readings	.....	.....	.....	2	2	2	2	.....	.....	.....

TABLE 4—DURATION AND SEQUENCE OF SPECIFIC ACTIVITIES FOR TEST 4, IN MINUTES—Continued
[42 CFR part 84, subpart H]

Activity	Service time—									
	3 minutes	5 minutes	10 minutes	15 minutes	30 minutes	45 minutes	1 hour	2 hours	3 hours	4 hours
Walks at 4.8 km. (3 miles) per hour	1		1			2	6			
Pulls 20 kg. (45 pound) weight to 5 feet						60 times in 5 minutes	60 times in 5 minutes			
Carries 20 kg. (45 pound) weight and walks at 4.8 km. (3 miles) per hour						3	3			
Sampling and readings						2	2			

[1] Treadmill shall be inclined 15° from vertical and operated at a speed of 30 cm. (1 foot) per second.
[2] Perform test No. 1 for 30-minute apparatus; then perform test No. 4 for 1-hour apparatus; then perform test No. 1 for 30-minute apparatus.
[3] Perform test No. 1 for 1-hour apparatus; then perform test No. 4 for 1-hour apparatus; then perform test No. 1 for 1-hour apparatus.
[4] Perform test No. 1 for 1-hour apparatus; then perform test No. 4 for 1-hour apparatus; then perform test No. 1 for 1-hour apparatus twice (i.e., two one-hour tests).

Subpart I—Gas Masks

§ 84.110 Gas masks; description.

(a) Gas masks including all completely assembled air purifying masks designed for use as respiratory protection during entry into atmospheres not immediately dangerous to life or health or escape only from hazardous atmospheres containing adequate oxygen to support life are described as follows:

(1) *Front-mounted or back-mounted gas mask.* A gas mask which consists of a full facepiece, a breathing tube, a canister at the front or back, a canister harness, and associated connections.

(2) *Chin-style gas mask.* A gas mask which consists of a full facepiece, a canister which is usually attached to the facepiece, and associated connections.

(3) *Escape gas mask.* A gas mask designed for use during escape only from hazardous atmospheres which consists of a facepiece or mouthpiece, a canister, and associated connections.

(b) Gas masks shall be further described according to the types of gases or vapors against which they are designed to provide respiratory protection, as follows:

Type of front-mounted or back-mounted gas mask:
- Acid gas [1 2 3]
- Ammonia
- Carbon monoxide
- Organic Vapor [1 2 3]
- Other gas(es) and vapor(s) [1 2 3]
- Combination of two or more of the above gases and vapors. [1 2 3]
- Combination of acid gas, ammonia, carbon monoxide, and organic vapors. [1 2 3]

Type of chin-style gas mask:
- Acid gas [1 2 3]
- Ammonia
- Carbon monoxide
- Organic vapor [1 2 3]
- Other gas(es) and vapor [1 2 3]
- Combination of two or more of the above gases and vapors. [1 2 3]

Type of escape gas mask:
- Acid gas [1 2 3 4]
- Ammonia [4]
- Carbon monoxide
- Organic vapor [1 2 3 4]
- Other gas(s) and vapor(s) [1 2 3 4]
- Combination of two or more of the above gases and vapors. [1 2 3 4]

[1] Approval may be for acid gases or organic vapors as a class or for specific acid gases or organic vapors.
[2] Not for use against gases or vapors with poor warning properties (except where MSHA or Occupational Safety and Health Administration standards permit such use for a specific gas or vapor), or those which generate high heats or reaction with sorbent materials in the canister.
[3] Use of the gas mask may be limited by factors such as lower explosive limit, toxicological effects, and facepiece fit. Limitations on gas mask service life and sorbent capacity limitations shall be specified by the applicant in instructions for selection, use and maintenance of the gas mask.
[4] Eye protection may be required in certain concentrations of gases and vapors.

(c) Gas masks for respiratory protection against gases and vapors other than those specified in paragraph (b) of this section, may be approved upon submittal of an application in writing for approval to the Certification and Quality Assurance Branch listing the gas or vapor and suggested maximum use concentration for the specific type of gas mask. The Institute will consider the application and accept or reject it on the basis of effect on the wearer's health and safety and any field experience in use of gas masks for such exposures. If the application is accepted, the Institute will test such masks in accordance with the requirements of this subpart.

§ 84.111 Gas masks; required components.

(a) Each gas mask described in § 84.110 shall, where its design requires, contain the following component parts:

(1) Facepiece or mouthpiece and noseclip;

(2) Canister or cartridge;

(3) Canister harness;

(4) External check valve; and

(5) Breathing tube.

(b) The components of each gas mask shall meet the minimum construction requirements set forth in subpart G of this part.

§ 84.112 Canisters and cartridges in parallel; resistance requirements.

Where two or more canisters or cartridges are used in parallel, their resistance to airflow shall be essentially equal.

§ 84.113 Canisters and cartridges; color and markings; requirements.

The color and markings of all canisters and cartridges or labels shall conform with the requirements of the American National Standards Institute, American National Standard for Identification of Air-Purifying Respirator Canisters and Cartridges, ANSI K13.1–1973. ANSI K13.1 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018. Copies may be inspected at the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

§ 84.114 Filters used with canisters and cartridges; location; replacement.

(a) Particulate matter filters used in conjunction with a canister or cartridge shall be located on the inlet side of the canister or cartridge.

(b) Filters shall be incorporated in or firmly attached to the canister or cartridge and each filter assembly shall, where applicable, be designed to permit its easy removal from and replacement in the canister or cartridge.

§ 84.115 Breathing tubes; minimum requirements.

Flexible breathing tubes used in conjunction with gas masks shall be designed and constructed to prevent:

(a) Restriction of free head movement;

(b) Disturbance of the fit of facepieces or mouthpieces;

(c) Interference with the wearer's activities; and

(d) Shutoff of airflow due to kinking, or from chin or arm pressure.

§ 84.116 Harnesses; installation and construction; minimum requirements.

(a) Each gas mask shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the gas mask in position against the wearer's body.

(b) Harnesses shall be designed and constructed to permit easy removal and replacement of gas mask parts, and where applicable, provide for holding a full facepiece in the ready position when not in use.

§ 84.117 Gas mask containers; minimum requirements.

(a) Gas masks shall be equipped with a substantial, durable container bearing markings which show the applicant's name, the type and commercial designation of mask it contains and all appropriate approval labels.

(b) Containers for gas masks shall be designed and constructed to permit easy removal of the mask.

§ 84.118 Half-mask facepieces, full facepieces, and mouthpieces; fit; minimum requirements.

(a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either:

(1) By providing more than one facepiece size; or

(2) By providing one facepiece size which will fit varying facial shapes and sizes.

(b) Full facepieces shall provide for optional use of corrective spectacles or lenses, which shall not reduce the respiratory protective qualities of the gas mask.

(c) Half-mask facepieces shall not interfere with the fit of common industrial safety spectacles, as determined by the Institute's facepiece tests in § 84.124.

(d) Gas masks with mouthpieces shall be equipped with noseclips which are securely attached to the mouthpiece or gas mask and provide an airtight seal.

(e) Facepieces shall be designed to prevent eyepiece fogging.

§ 84.119 Facepieces; eyepieces; minimum requirements.

(a) Full facepieces shall be designed and constructed to provide adequate vision which is not distorted by the eye.

(b) All eyepieces shall be designed and constructed to be impact and penetration resistant. Federal Specification, Mask, Air Line: and Respirator, Air Filtering, Industrial, GGG–M–125d, October 11, 1965 with interim amendment-1, July 30, 1969, is an example of an appropriate standard for determining impact and penetration resistance. Copies of GGG–M–125d may be obtained from the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888.

§ 84.120 Inhalation and exhalation valves; minimum requirements.

(a) Inhalation and exhalation valves shall be provided where necessary and protected against damage and distortion.

(b) Inhalation valves shall be designed and constructed to prevent excessive exhaled air from adversely affecting cartridges, canisters, and filters.

(c) Exhalation valves shall be protected against external influence, and designed and constructed to prevent inward leakage of contaminated air.

§ 84.121 Head harnesses; minimum requirements.

(a) Facepieces shall be equipped with adjustable and replaceable head harnesses, designed and constructed to provide adequate tension during use and an even distribution of pressure over the entire area in contact with the face.

(b) Mouthpieces shall be equipped, where applicable, with adjustable and replaceable harnesses designed and constructed to hold the mouthpiece in place.

§ 84.122 Breathing resistance test; minimum requirements.

(a) Resistance to airflow will be measured in the facepiece or mouthpiece of a gas mask mounted on a breathing machine both before and after each test conducted in accordance with §§ 84.124, 84.125, and 84.126, with air flowing at a continuous rate of 85 liters per minute.

(b) The maximum allowable resistance requirements for gas masks are as follows:

MAXIMUM RESISTANCE
[mm. water-column height]

Type of gas mask	Inhalation		Exhalation
	Initial	Final [1]	
Front-mounted or back-mounted (without particulate filter)	60	75	20
Front-mounted or back-mounted (with approved particulate filter)	70	85	20
Chin-style (without particulate filter)	40	55	20
Chin-style (with approved particulate filter)	65	80	20
Escape (without particulate filter)	60	75	20
Escape (with approved particulate filter)	70	85	20

[1] Measured at end of the service life specified in Tables 5, 6, and 7 of this subpart.

§ 84.123 Exhalation valve leakage test.

(a) Dry exhalation valves and valve seats will be subjected to a suction of 25 mm. water-column height while in a normal operating position.

(b) Leakage between the valve and valve seat shall not exceed 30 milliliters per minute.

§ 84.124 Facepiece tests; minimum requirements.

(a) The complete gas mask will be fitted to the faces of persons having varying facial shapes and sizes.

(b) Where the applicant specifies a facepiece size or sizes for the gas mask, together with the approximate measurements of faces they are designed to fit, the Institute will insure that test subjects suit such facial measurements.

(c) Any gas mask parts which must be removed to perform the facepiece or mouthpiece fit test shall be replaceable without special tools and without disturbing the facepiece or mouthpiece fit.

(d) The facepiece or mouthpiece fit test, using positive or negative pressure recommended by the applicant and described in his instructions will be used before each test specified in paragraph (e) of this section, and in § 84.125.

(e)(1) Each wearer will enter a chamber containing 100 p.p.m. isoamyl acetate vapor for a half-mask facepiece and 1,000 p.p.m. isoamyl acetate vapor for a full facepiece or mouthpiece.

(2) The facepiece or mouthpiece may be adjusted, if necessary, in the test chamber before starting the tests.

(3) Each wearer will remain in the chamber for 8 minutes while performing the following activities:

(i) Two minutes, nodding and turning head;

(ii) Two minutes, calisthenic arm movements;

(iii) Two minutes, running in place; and

(iv) Two minutes, pumping with a tire pump into a 28 liter (1 cubic foot) container.

(4) Each wearer shall not detect the odor of isoamyl acetate during the test.

§ 84.125 Particulate tests; canisters containing particulate filters; minimum requirements.

Gas mask canisters containing filters for protection against particulates (e.g. dusts, fumes, mists, and smokes) in combination with gases, vapors, or gases and vapors, shall also comply with the requirements as prescribed in §§ 84.170 through 84.183, except for the airflow resistance test of § 84.181.

§ 84.126 Canister bench tests; minimum requirements.

(a)(1) Bench tests, except for carbon monoxide tests, will be made on an apparatus that allows the test atmosphere at 50±5 percent relative humidity and room temperature (25±2.5 °C.) to enter the canister continuously at concentrations and rates of flow specified in Tables 5, 6, and 7 of this subpart.

(2) Three canisters will be removed from containers and tested as received from the applicant.

(3) Two canisters, other than those described in paragraph (a)(2) of this section, will be equilibrated at room temperature by passing 25 percent relative humidity air through them at 64 liters per minute for 6 hours.

(4) Two canisters, other than those described in paragraphs (a) (2) and (3)

of this section, will be equilibrated at room temperature by passing 85 percent relative humidity air through them at 64 liters per minute for 6 hours.

(5) The equilibrated canisters will be resealed, kept in an upright position at room temperature, and tested within 18 hours.

(b) Front-mounted and back-mounted gas mask canisters will be tested and shall meet the minimum requirements set forth in Table 5 of this subpart.

(c)(1) Front-mounted, and back-mounted, and chin-style canisters designated as providing respiratory protection against gases, ammonia, organic vapors, carbon monoxide and particulate contaminants shall have a window or other indicator to warn the gas mask wearer when the canister will no longer satisfactorily remove carbon monoxide from the inhaled air.

(2) Other types of front- and back-mounted canisters may also be equipped with a window or other indicator to warn of imminent leakage of other gases or vapors.

(3) The window indicator canisters will be tested as regular canisters, but shall show a satisfactory indicator change or other warning before the allowable canister penetration has occurred.

(d) Chin-style gas mask canisters shall meet the minimum requirements set forth in Table 6 of this subpart.

(e) Escape gas mask canisters shall meet the minimum requirements set forth in Table 7 of this subpart.

TABLES TO SUBPART I OF PART 84

TABLE 5—CANISTER BENCH TESTS AND REQUIREMENTS FOR FRONT-MOUNTED AND BACK-MOUNTED GAS MASK CANISTERS

[42 CFR part 84, subpart I]

Canister type	Test condition	Test atmosphere			Number of tests	Maximum allowable penetratin (parts per million)	Minimum service life (minutes) [1]
		Gas or vapor	Concentration (parts per million)	Flow rate (liters per minute)			
Acid gas	As received	SO_2	20,000	64	3	5	12
	Equilibrated	Cl_2	20,000	64	3	5	12
		SO_2	20,000	32	4	5	12
		Cl_2	20,000	32	4	5	12
Organic vapor	As received	CCl_4	20,000	64	3	5	12
	Equilibrated	CCl_4	20,000	32	4	5	12
Ammonia	As received	NH_3	30,000	64	3	50	12
	Equilibrated	NH_3	30,000	32	4	50	12
Carbon monoxide	As received	CO	20,000	[4] 64	2	([3])	60
	Equilibrated	CO	5,000	[2] 32	3	([3])	60
		CO	3,000	[2] 32	3	([3])	60
Combination of 2 or 3 of above types [5]							
Combination of all above types [6]							

[1] Minimum life will be determined at the indicated penetration.
[2] Relative humidity of test atmosphere will be 95±3pct; temperature of test atmosphere will be 25±2.5 °C.
[3] Maximum allowable CO penetration will be 385 cm^3 during the minimum life. The penetration shall not exceed 500 p/m during this time.
[4] Relative humidity of test atmosphere will be 95±3pct; temperature of test atmosphere entering the test fixture will be 0±2.5 °C – 0 °C.
[5] Test conditions and requirements will be applicable as shown in this table.
[6] Test conditions and requirements will be applicable as shown in this table, except the minimum service lives for acid gas, organic vapor, and ammonia will be 6 min instead of 12 min.

TABLE 6—CANISTER BENCH TESTS AND REQUIREMENTS FOR CHIN-STYLE GAS MASK CANISTERS

[42 CFR part 84, subpart I]

Canister type	Test condition	Test atmosphere			Number of tests	Maximum allowable penetration (parts per million)	Minimum service life (minutes) [1]
		Gas or vapor	Concentration (parts per million)	Flow rate (liters per minute)			
Acid gas	As received Equilibrated	SO_2	50,000	64	3	5	12

TABLE 6—CANISTER BENCH TESTS AND REQUIREMENTS FOR CHIN-STYLE GAS MASK CANISTERS—Continued

[42 CFR part 84, subpart I]

Canister type	Test condition	Test atmosphere			Number of tests	Maximum allowable penetration (parts per million)	Minimum service life (minutes) [1]
		Gas or vapor	Concentration (parts per million)	Flow rate (liters per minute)			
		Cl_2	5,000	64	3	5	12
		SO_2	5,000	32	4	5	12
		Cl_2	5,000	32	4	5	12
Organic vapor	As received Equilibrated	CCl_4	5,000	64	3	5	12
		CCl_4	5,000	32	4	5	12
Ammonia	As received Equilibrated	NH_3	5,000	64	3	50	12
	As received Equilibrated	NH_3	5,000	32	4	50	12
Carbon monoxide	As received	CO	20,000	[2] 64	2	([3])	60
		CO	5,000	[4] 32	3	([3])	60
		CO	3,000	[2] 32	3	([3])	60
Combination of 2 or 3 of above types [5]							
Combination of all above types [6]							

[1] Minimum life will be determined at the indicated penetration.
[2] Relative humidity of test atmosphere will be 95±3pct; temperature of test atmosphere will be 25±2.5 ° C.
[3] Maximum allowable CO penetration will be 385 cm^3 during the minimum life. The penetration shall not exceed 500 p/m during this time.
[4] Relative humidity of test atmosphere will be 95±3pct; temperature of test atmosphere entering the test fixture will be 0±2.5 °C – 0° C.
[5] Test conditions and requirements will be applicable as shown in this table.
[6] Test conditions and requirements will be applicable as shown in this table, except the minimum service lives for acid gas, organic vapor, and ammonia will be 6 min instead of 12 min.

TABLE 7—CANISTER BENCH TESTS AND REQUIREMENTS FOR ESCAPE GAS MASK CANISTERS

[42 CFR part 84, subpart I]

Canister type	Test condition	Test atmosphere			Number of tests	Maximum allowable penetration (parts per million)	Minimum service life (minutes) [1]
		Gas or vapor	Concentration (parts per million)	Flow rate (liters per minute)			
Acid gas	As received	SO_2	5,000	64	3	5	12
	Equilibrated	Cl_2	5,000	64	3	5	12
		SO_2	5,000	32	4	5	12
		Cl_2	5,000	32	4	5	12
Organic vapor	As received	CCl_4	5,000	64	3	5	12
	Equilibrated	CCl_4	5,000	32	4	5	12
Ammonia	As received	NH_3	5,000	64	3	50	12
	Equilibrated	NH_3	5,000	32	4	50	12
Carbon monoxide	As received	CO	10,000	[2] 32	2	([3])	[4] 60
		CO	5,000	[5] 32	3	([3])	60
		CO	3,000	[2] 32	3	([3])	60

[1] Minimum life will be determined at the indicated penetration.
[2] Relative humidity of test atmosphere will be 95 ±3 pct; temperature of test atmosphere will be 25 ±2.5 °C.
[3] Maximum allowable CO penetration will be 385 cm^3 during the minimum life. The penetration shall not exceed 500 p/m during this time.
[4] If effluent temperature exceeds 100° C during this test, the escape gas mask shall be equipped with an effective heat exchanger.
[5] Relative humidity of test atmosphere will be 95 ±3 pct; temperature of test atmosphere entering the test fixture will be 0 ±2.5 °C – 0 °C.

Subpart J—Supplied-Air Respirators

§ 84.130 Supplied-air respirators; description.

Supplied-air respirators, including all completely assembled respirators designed for use as respiratory protection during entry into and escape from atmospheres not immediately dangerous to life or health are described as follows:

(a) *Type "A" supplied-air respirators.* A hose mask respirator, for entry into and escape from atmospheres not immediately dangerous to life or health, which consists of a motor-driven or hand-operated blower that permits the free entrance of air when the blower is not operating, a strong large-diameter hose having a low resistance to airflow, a harness to which the hose and the life-line are attached and a tight-fitting facepiece.

(b) *Type "AE" supplied-air respirators.* A Type "A" supplied-air respirator equipped with additional devices designed to protect the wearer's head and neck against impact and abrasion from rebounding abrasive material, and with shielding material such as plastic, glass, woven wire, sheet metal, or other suitable material to protect the window(s) of facepieces, hoods, and helmets which do not unduly interfere with the wearer's vision and permit easy access to the external surface of such window(s) for cleaning.

(c) *Type "B" supplied-air respirators.* A hose mask respirator, for entry into and escape from atmospheres not immediately dangerous to life or health, which consists of a strong large-diameter hose with low resistance to airflow through which the user draws inspired air by means of his lungs alone, a harness to which the hose is attached, and a tight-fitting facepiece.

(d) *Type "BE" supplied-air respirators.* A type "B" supplied-air respirator equipped with additional devices designed to protect the wearer's head and neck against impact and abrasion from rebounding abrasive material, and with shielding material such as plastic, glass, woven wire, sheet metal, or other suitable material to protect the window(s) of facepieces, hoods, and helmets which do not unduly interfere with the wearer's vision and permit easy access to the external surface of such window(s) for cleaning.

(e) *Type "C" supplied-air respirators.* An airline respirator, for entry into and escape from atmospheres not immediately dangerous to life or health, which consists of a source of respirable breathing air, a hose, a detachable coupling, a control valve, orifice, a demand valve or pressure demand valve, an arrangement for attaching the hose to the wearer, and a facepiece, hood, or helmet.

(f) *Type "CE" supplied-air respirators.* A type "C" supplied-air respirator equipped with additional devices designed to protect the wearer's head and neck against impact and abrasion from rebounding abrasive material, and with shielding material such as plastic, glass, woven wire, sheet metal, or other suitable material to protect the window(s) of facepieces, hoods, and helmets which do not unduly interfere with the wearer's vision and permit easy access to the external surface of such window(s) for cleaning.

§ 84.131 Supplied-air respirators; required components.

(a) Each supplied-air respirator described in § 84.130 shall, where its design requires, contain the following component parts:

(1) Facepiece, hood, or helmet;

(2) Air supply valve, orifice, or demand or pressure-demand regulator;

(3) Hand operated or motor driven air blower;

(4) Air supply hose;

(5) Detachable couplings;

(6) Flexible breathing tube; and

(7) Respirator harness.

(b) The component parts of each supplied-air respirator shall meet the minimum construction requirements set forth in subpart G of this part.

§ 84.132 Breathing tubes; minimum requirements.

Flexible breathing tubes used in conjunction with supplied-air respirators shall be designed and constructed to prevent:

(a) Restriction of free head movement;

(b) Disturbance of the fit of facepieces, mouthpieces, hoods, or helmets;

(c) Interference with the wearer's activities; and

(d) Shutoff of airflow due to kinking, or from chin or arm pressure.

§ 84.133 Harnesses; installation and construction; minimum requirements.

(a) Each supplied-air respirator shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearer's body.

(b) Harnesses shall be designed and constructed to permit easy removal and replacement of respirator parts, and where applicable, provide for holding a full facepiece in the ready position when not in use.

§ 84.134 Respirator containers; minimum requirements.

Supplied-air respirators shall be equipped with a substantial, durable container bearing markings which show the applicant's name, the type and commercial designation of the respirator it contains, and all appropriate approval labels.

§ 84.135 Half-mask facepieces, full facepieces, hoods, and helmets; fit; minimum requirements.

(a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either:

(1) By providing more than one facepiece size; or

(2) By providing one facepiece size which will fit varying facial shapes and sizes.

(b) Full facepieces shall provide for optional use of corrective spectacles or lenses, which shall not reduce the respiratory protective qualities of the respirator.

(c) Hoods and helmets shall be designed and constructed to fit persons with various head sizes, provide for the optional use of corrective spectacles or lenses, and insure against any restriction of movement by the wearer.

(d) Facepieces, hoods, and helmets shall be designed to prevent eyepiece fogging.

§ 84.136 Facepieces, hoods, and helmets; eyepieces; minimum requirements.

(a) Facepieces, hoods, and helmets shall be designed and constructed to provide adequate vision which is not distorted by the eyepiece.

(b) All eyepieces except those on Types B, BE, C, and CE supplied-air respirators shall be designed and constructed to be impact and penetration resistant. Federal Specification, Mask, Air Line: and Respirator, Air Filtering, Industrial, GGG–M–125d, October 11, 1965 with interim amendment-1, July 30, 1969, is an example of an appropriate standard for determining impact and penetration resistance. Copies of GGG–M–125d may be obtained from the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888.

(c)(1) The eyepieces of AE, BE, and CE type supplied-air respirators shall be shielded by plastic, glass, woven wire, sheet metal, or other suitable material which does not interfere with the vision of the wearer.

(2) Shields shall be mounted and attached to the facepiece to provide easy access to the external surface of the eyepiece for cleaning.

§ 84.137 Inhalation and exhalation valves; check valves; minimum requirements.

(a) Inhalation and exhalation valves shall be provided where necessary and protected against distortion.

(b) Exhalation valves shall be:

(1) Protected against damage and external influence; and

(2) Designed and constructed to prevent inward leakage of contaminated air.

(c) Check valves designed and constructed to allow airflow toward the facepiece only shall be provided in the connections to the facepiece or in the hose fitting near the facepiece of all Type A, AE, B, and BE supplied-air respirators.

§ 84.138 Head harnesses; minimum requirements.

Facepieces shall be equipped with adjustable and replaceable head harnesses which are designed and constructed to provide adequate tension

during use, and an even distribution of pressure over the entire area in contact with the face.

§ 84.139 Head and neck protection; supplied-air respirators; minimum requirements.

Type AE, BE, and CE supplied-air respirators shall be designed and constructed to provide protection against impact and abrasion from rebounding abrasive materials to the wearer's head and neck.

§ 84.140 Air velocity and noise levels; hoods and helmets; minimum requirements.

Noise levels generated by the respirator will be measured inside the hood or helmet at maximum airflow obtainable within pressure and hose length requirements and shall not exceed 80 dBA.

§ 84.141 Breathing gas; minimum requirements.

(a) Breathing gas used to supply supplied-air respirators shall be respirable breathing air and contain no less than 19.5 volume-percent of oxygen.

(b) Compressed, gaseous breathing air shall meet the applicable minimum grade requirements for Type I gaseous air set forth in the Compressed Gas Association Commodity Specification for Air, G–7.1, 1966 (Grade D or higher quality). G–7.1 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018. Copies may be inspected at the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) Compressed, liquefied breathing air shall meet the applicable minimum grade requirements for Type II liquid air set forth in the Compressed Gas Association Commodity Specification for Air, G–7.1, 1966 (Grade B or higher quality). G–7.1 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018. Copies may be inspected at the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

§ 84.142 Air supply source; hand-operated or motor driven air blowers; Type A supplied-air respirators; minimum requirements.

(a) Blowers shall be designed and constructed to deliver an adequate amount of air to the wearer with either direction of rotation, unless constructed to permit rotation in one direction only, and to permit the free entrance of air to the hose when the blower is not operated.

(b) No multiple systems, whereby more than one user is supplied by one blower, will be approved, unless each hose line is connected directly to a manifold at the blower.

§ 84.143 Terminal fittings or chambers; Type B supplied-air respirators; minimum requirements.

(a) Blowers or connections to air supplies providing positive pressures shall not be approved for use on Type B supplied-air respirators.

(b) Terminal fittings or chambers employed in Type B supplied-air respirators, shall be:

(1) Installed in the inlet of the hose.

(2) Designed and constructed to provide for the drawing of air through corrosion resistant material arranged so as to be capable of removing material larger than 0.149 mm. in diameter (149 micrometers, 100-mesh, U.S. Standard sieve).

(3) Installed to provide a means for fastening or anchoring the fitting or chamber in a fixed position in a zone of respirable air.

§ 84.144 Hand-operated blower test; minimum requirements.

(a) Hand-operated blowers shall be tested by attaching them to a mechanical drive and operating them 6 to 8 hours daily for a period of 100 hours at a speed necessary to deliver 50 liters of air per minute through each completely assembled respirator. Each respirator shall be equipped with the maximum length of hose with which the device is to be approved and the hose shall be connected to each blower or manifold outlet designed for hose connections.

(b) The crank speed of the hand-operated blower shall not exceed 50 revolutions per minute in order to deliver the required 50 liters of air per minute to each facepiece.

(c) The power required to deliver 50 liters of air per minute to each wearer through the maximum length of hose shall not exceed one-fiftieth horsepower, and the torque shall not exceed a force of 2.3 kg. (5 pounds) on a 20 cm. (8-inch) crank, as defined in § 84.146.

(d) The blower shall operate throughout the period without failure or indication of excessive wear of bearings or other working parts.

§ 84.145 Motor-operated blower test; minimum requirements.

(a) Motor-operated blowers shall be tested by operating them at their specified running speed 6 to 8 hours daily for a period of 100 hours when assembled with the kind and maximum length of hose for which the device is to be approved and when connected to each blower or manifold outlet designed for hose connections.

(b) The connection between the motor and the blower shall be so constructed that the motor may be disengaged from the blower when the blower is operated by hand.

(c) The blower shall operate throughout the period without failure or indication of excessive wear of bearings or other working parts.

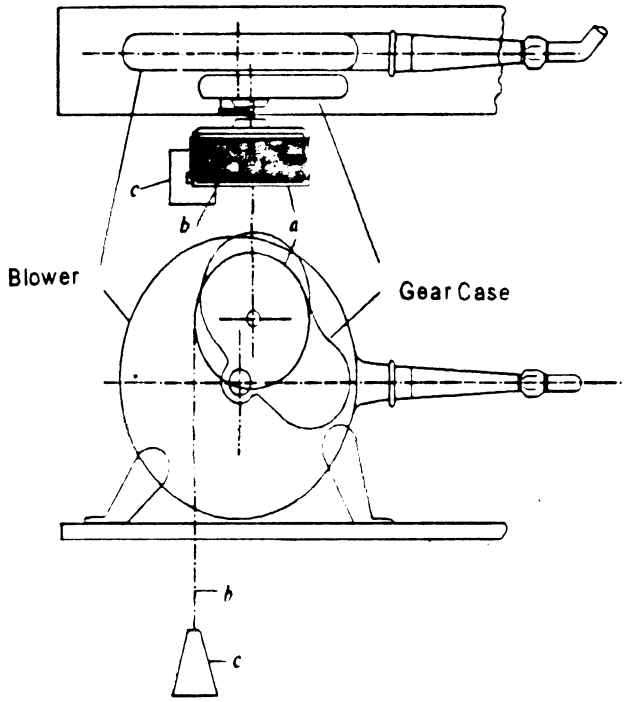
(d) Where a blower, which is ordinarily motor driven, is operated by hand, the power required to deliver 50 liters of air per minute to each wearer through the maximum length of hose shall not exceed one-fiftieth horsepower, and the torque shall not exceed a force of 2.3 kg. (5 pounds) on a 20 cm. (8-inch) crank, as defined in § 84.146.

(e) Where the respirator is assembled with the facepiece and 15 m. (50 feet) of the hose for which it is to be approved, and when connected to one outlet with all other outlets closed and operated at a speed not exceeding 50 revolutions of the crank per minute, the amount of air delivered into the respiratory-inlet covering shall not exceed 150 liters per minute.

§ 84.146 Method of measuring the power and torque required to operate blowers.

As shown in Figure 1 of this section, the blower crank is replaced by a wooden drum, a (13 cm. (5 inches) in diameter is convenient). This drum is wound with about 12 m. (40 feet) of No. 2 picture cord, b. A weight, c, of sufficient mass to rotate the blower at the desired speed is suspended from this wire cord. A mark is made on the cord about 3 to 4.5 m. (10 to 15 feet) from the weight, c. Another mark is placed at a measured distance (6–9 m./20–30 feet is convenient) from the first. These are used to facilitate timing. To determine the torque or horsepower required to operate the blower, the drum is started in rotation manually at or slightly above the speed at which the power measurement is to be made. The blower is then permitted to assume constant speed, and then as the first mark on the wire leaves the drum, a stopwatch is started. The watch is stopped when the second mark leaves the drum. From these data the foot-pounds per minute and the torque may be calculated.

FIGURE 1—APPARATUS FOR MEASURING POWER REQUIRED TO OPERATE BLOWER. (42 CFR PART 84, SUBPART J, § 84.146)



§ 84.147 Type B supplied-air respirator; minimum requirements.

No Type B supplied-air respirator shall be approved for use with a blower or with connection to an air supply device at positive pressures.

§ 84.148 Type C supplied-air respirator, continuous flow class; minimum requirements.

(a) Respirators tested under this section shall be approved only when they supply respirable air at the pressures and quantities required.

(b) The pressure at the inlet of the hose connection shall not exceed 863 kN/m.^{2} (125 pounds per square inch gage).

(c) Where the pressure at any point in the supply system exceeds 863 kN/m.^{2} (125 pounds per square inch gage), the respirator shall be equipped with a pressure-release mechanism that will prevent the pressure at the hose connection from exceeding 863 kN/m.^{2} (125 pounds per square inch gage) under any conditions.

§ 84.149 Type C supplied-air respirator, demand and pressure demand class; minimum requirements.

(a) Respirators tested under this section shall be approved only when used to supply respirable air at the pressures and quantities required.

(b) The manufacturer shall specify the range of air pressure at the point of attachment of the air-supply hose to the air-supply system, and the range of hose length for the respirator. For example, he might specify that the respirator be used with compressed air at pressures ranging from 280–550 kN/m.^{2} (40 to 80 pounds per square inch) with from 6 to 76 m. (15 to 250 feet) of air-supply hose.

(c) The specified air pressure at the point of attachment of the hose to the air-supply system shall not exceed 863 kN/m.^{2} (125 pounds per square inch gage).

(d)(1) Where the pressure in the air-supply system exceeds 863 kN/m.^{2} (125 pounds per square inch gage), the respirator shall be equipped with a pressure-release mechanism that will prevent the pressure at the point of attachment of the hose to the air-supply system from exceeding 863 kN/m.^{2} (125 pounds per square inch gage).

(2) The pressure-release mechanism shall be set to operate at a pressure not more than 20 percent above the manufacturer's highest specified pressure. For example, if the highest specified pressure is 863 kN/m.^{2} (125 pounds per square inch), the pressure-release mechanism would be set to operate at a maximum of 1,035 kN/m.^{2} (150 pounds per square inch).

§ 84.150 Air-supply line tests; minimum requirements.

Air supply lines employed on Type A, Type B, and Type C supplied-air respirators shall meet the minimum test requirements set forth in Table 8 of this subpart.

§ 84.151 Harness test; minimum requirements.

(a)(1) Shoulder straps employed on Type A supplied-air respirators shall be tested for strength of material, joints, and seams and must separately withstand a pull of 113 kg. (250 pounds) for 30 minutes without failure.

(2) Belts, rings, and attachments for life lines must withstand a pull of 136 kg. (300 pounds) for 30 minutes without failure.

(3) The hose shall be firmly attached to the harness so as to withstand a pull of 113 kg. (250 pounds) for 30 minutes without separating, and the hose attachments shall be arranged so that the pull or drag of the hose behind an advancing wearer does not disarrange the harness or exert pull upon the facepiece.

(4) The arrangement and suitability of all harness accessories and fittings will be considered.

(b)(1) The harness employed on Type B supplied-air respirators shall not be uncomfortable, disturbing, or interfere with the movements of the wearer.

(2) The harness shall be easily adjustable to various sizes.

(3) The hose shall be attached to the harness in a manner that will withstand a pull of 45 kg. (100 pounds) for 30 minutes without separating or showing signs of failure.

(4) The design of the harness and attachment of the line shall permit dragging the maximum length of hose considered for approval over a concrete floor without disarranging the harness or exerting a pull on the facepiece.

(5) The arrangement and suitability of all harness accessories and fittings will be considered.

(c) The harness employed on Type C respirators shall be similar to that required on the Type B respirator, or, it may consist of a simple arrangement for attaching the hose to a part of the wearer's clothing in a practical manner that prevents a pull equivalent to dragging the maximum length of the hose over a concrete floor from exerting pull upon the respiratory-inlet covering.

(d) Where supplied-air respirators have a rigid or partly rigid head covering, a suitable harness shall be required to assist in holding this covering in place.

§ 84.152 Breathing tube test; minimum requirements.

(a)(1) Type A and Type B supplied-air respirators shall employ one or two flexible breathing tubes of the nonkinking type which extend from the facepiece to a connecting hose coupling attached to the belt or harness.

(2) The breathing tubes employed shall permit free head movement, insure against closing off by kinking or by chin or arm pressure, and they shall not create a pull that will loosen the facepiece or disturb the wearer.

(b) Breathing tubes employed on Type C supplied-air respirators of the continuous flow class shall meet the minimum requirements set forth in paragraph (a) of this section, however, an extension of the connecting hose may be employed in lieu of the breathing tubes required.

(c)(1) A flexible, nonkinking type breathing tube shall:

(i) Be employed on Type C supplied-air respirators of the demand and pressure-demand class; and

(ii) Extend from the facepiece to the demand or pressure-demand valve, except where the valve is attached directly to the facepiece.

(2) The breathing tube shall permit free head movement, insure against closing off by kinking or by chin or arm pressure, and shall not create a pull that will loosen the facepiece or disturb the wearer.

§ 84.153 Airflow resistance test, Type A and Type AE supplied-air respirators; minimum requirements.

(a) Airflow resistance will be determined when the respirator is completely assembled with the respiratory-inlet covering, the air-supply device, and the maximum length of air-supply hose coiled for one-half its length in loops 1.5 to 2.1 m. (5 to 7 feet) in diameter.

(b) The inhalation resistance, drawn at the rate of 85 liters (3 cubic feet) per minute when the blower is not operating or under any practical condition of blower operation shall not exceed the following amounts:

Maximum length of hose for which respirator is approved		Maximum resistance, water column height	
Feet	Meters	Inches	Millimeters
75	23	1.5	38
150	46	2.5	64
250	76	3.5	89
300	91	4.0	102

(c) The exhalation resistance shall not exceed 25 mm. (1 inch) of water-column height at a flow rate of 85 liters (3 cubic feet) per minute when the blower is not operating or under any practical condition of blower operation.

§ 84.154 Airflow resistance test; Type B and Type BE supplied-air respirators; minimum requirements.

(a) Airflow resistance shall be determined when the respirator is completely assembled with the respiratory-inlet covering and the hose in the maximum length to be considered for approval, coiled in loops 1.5 to 2.1 m. (5 to 7 feet) in diameter.

(b) Airflow resistance shall not exceed 38 mm. (1.5 inches) of water-column height to air drawn at the flow rate of 85 liters (3 cubic feet) per minute.

(c) The exhalation resistance shall not exceed 25 mm. (1 inch) of water-column height at this flow rate.

§ 84.155 Airflow resistance test; Type C supplied-air respirator, continuous flow class and Type CE supplied-air respirator; minimum requirements.

The resistance to air flowing from the respirator shall not exceed 25 mm. (1 inch) of water-column height when the air flow into the respiratory-inlet covering is 115 liters (4 cubic feet) per minute.

§ 84.156 Airflow resistance test; Type C supplied-air respirator, demand class; minimum requirements.

(a) Inhalation resistance shall not exceed 50 millimeters (2 inches) of water at an air flow of 115 liters (4 cubic feet) per minute.

(b) The exhalation resistance to a flow of air at a rate of 85 liters (3 cubic feet) per minute shall not exceed 25 millimeters (1 inch) of water.

§ 84.157 Airflow resistance test; Type C supplied-air respirator, pressure-demand class; minimum requirements.

(a) The static pressure in the facepiece shall not exceed 38 mm. (1.5 inches) of water-column height.

(b) The pressure in the facepiece shall not fall below atmospheric at inhalation airflows less than 115 liters (4 cubic feet) per minute.

(c) The exhalation resistance to a flow of air at a rate of 85 liters (3 cubic feet) per minute shall not exceed the static pressure in the facepiece by more than 51 mm. (2 inches) of water-column height.

§ 84.158 Exhalation valve leakage test.

(a) Dry exhalation valves and valve seats will be subjected to a suction of 25 mm. water-column height while in a normal operating position.

(b) Leakage between the valve and valve seat shall not exceed 30 milliliters per minute.

§ 84.159 Man tests for gases and vapors; supplied-air respirators; general performance requirements.

(a) Wearers will enter a chamber containing a gas or vapor as prescribed in §§ 84.160, 84.161, 84.162, and 84.163.

(b) Each wearer will spend 10 minutes in work to provide observations on freedom of the device from leakage. The freedom and comfort allowed the wearer will also be considered.

(c) Time during the test period will be divided as follows:

(1) *Five minutes.* Walking, turning head, dipping chin; and

(2) *Five minutes.* Pumping air with a tire pump into a 28-liter (1 cubic foot) container, or equivalent work.

(d) No odor of the test gas or vapor shall be detected by the wearer in the air breathed during any such test, and the wearer shall not be subjected to any undue discomfort or encumbrance because of the fit, air delivery, or other features of the respirator during the testing period.

§ 84.160 Man test for gases and vapors; Type A and Type AE respirators; test requirements.

(a) The completely assembled respirator will be worn in a chamber containing 0.1±0.025 percent isoamyl acetate vapor, and the blower, the intake of the hose, and not more than 25 percent of the hose length will be located in isoamyl acetate-free air.

(b) The man in the isoamyl acetate atmosphere will draw his inspired air through the hose, connections, and all parts of the air device by means of his lungs alone (blower not operating).

(c) The 10-minute work test will be repeated with the blower in operation at any practical speed up to 50 revolutions of the crank per minute.

§ 84.161 Man test for gases and vapors; Type B and Type BE respirators; test requirements.

(a) The completely assembled respirator will be worn in a chamber containing 0.1±0.025 percent isoamyl acetate vapor, and the intake of the hose, and not more than 25 percent of the hose length will be located in isoamyl acetate-free air.

(b) The man in the isoamyl acetate atmosphere will draw his inspired air through the hose and connections by means of his lungs alone.

§ 84.162 Man test for gases and vapors; Type C respirators, continuous-flow class and Type CE supplied-air respirators; test requirements.

(a) The completely assembled respirator will be worn in a chamber containing 0.1±0.025 percent isoamyl acetate vapor, the intake of the hose will be connected to a suitable source of respirable air, and not more than 25 percent of the hose length will be located in isoamyl acetate-free air.

(b) The minimum flow of air required to maintain a positive pressure in the respiratory-inlet covering throughout the entire breathing cycle will be supplied to the wearer, provided however, that airflow shall not be less than 115 liters per minute for tight-fitting and not less than 170 liters per minute for loose-fitting respiratory inlet-coverings.

(c) The test will be repeated with the maximum rate of flow attainable within specified operating pressures.

§ 84.163 Man test for gases and vapors; Type C supplied-air respirators, demand and pressure-demand classes; test requirements.

(a) The completely assembled respirator will be worn in a chamber containing 0.1±0.025 percent isoamyl acetate vapor, the intake of the hose will be connected to a suitable source of respirable air, and not more than 25 percent of the hose length will be located in isoamyl acetate-free air.

(b) The test will be conducted at the minimum pressure with the maximum hose length and will be repeated at the maximum pressure with the minimum hose length.

TABLE TO SUBPART J OF PART 84

TABLE 8—AIR-SUPPLY-LINE REQUIREMENTS AND TESTS

[42 CFR part 84, subpart J]

Specific requirements	Requirements for the air-supply lines of the indicated type of supplied-air respirators		
	Type A	Type B	Type C
Length of hose	Maximum of 91 m. (300 feet), in multiples of 7.6 m. (25 feet).	Maximum of 23 m. (75 feet) in multiples of 7.6 m. (25 feet).	Maximum of 91 m. (300 feet) in multiples of 7.6 m. (25 feet). It will be permissible for the applicant to supply hose of the approved type of shorter length than 7.6 m. (25 feet) provided it meets the requirements of the part.
Air flow	None	None	The air-supply hose with air regulating valve or orifice shall permit a flow of not less than 115 liters (4 cubic feet) per minute to tight-fitting and 170 liters (6 cubic feet) per minute to loose-fitting respiratory-inlet coverings through the maximum length of hose for which approval is granted and at the minimum specified air-supply pressure. The maximum flow shall not exceed 425 liters (15 cubic feet) per minute at the maximum specified air-supply pressure with the minimum length of hose for which approval is granted.
Air flow	.....do	.....do	The air-supply hose, detachable coupling, and demand valve of the demand class or pressure-demand valve of the pressure-demand class for Type C supplied-air respirators, demand and pressure-demand classes, shall be capable of delivering respirable air at a rate of not less than 115 liters (4 cubic feet) per minute to the respiratory-inlet covering at an inhalation resistance not exceeding 50 millimeters (2 inches) of water-column height measured in the respiratory-inlet covering with any combination of air-supply pressure and length of hose within the applicant's specified range of pressure and hose length. The airflow rate and resistance to inhalation shall be measured while the demand or pressure-demand valve is actuated 20 times per minute by a source of intermittent suction. The maximum rate of flow to the respiratory-inlet covering shall not exceed 425 liters (15 cubic feet) per minute under the specified operating conditions.

TABLE 8—AIR-SUPPLY-LINE REQUIREMENTS AND TESTS—Continued

[42 CFR part 84, subpart J]

Specific requirements	Requirements for the air-supply lines of the indicated type of supplied-air respirators		
	Type A	Type B	Type C
Air-regulating valve	.....do	.....do	If an air-regulating valve is provided, it shall be so designed that it will remain at a specific adjustment, which will not be affected by the ordinary movement of the wearer. The valve must be so constructed that the air supply with the maximum length of hose and at the minimum specified air-supply pressure will not be less than 115 liters (4 cubic feet) of air per minute to tight-fitting and 170 liters (6 cubic feet) of air per minute of loose-fitting respiratory inlet coverings for any adjustment of the valve. If a demand or pressure-demand valve replaces the air-regulating valve, it shall be connected to the air-supply at the maximum air pressure for which approval is sought by means of the minimum length of air-supply hose for which approval is sought. The outlet of the demand or pressure-demand valve shall be connected to a source of intermittent suction so that the demand or pressure-demand valve is actuated approximately 20 times per minute for a total of 100,000 inhalations. To expedite this test, the rate of actuation may be increased if mutually agreeable to the applicant and NIOSH. During this test the valve shall function without failure and without excessive wear of the moving parts. The demand or pressure-demand valve shall not be damaged in any way when subjected at the outlet to a pressure or suction of 25 cm. (10 inches) of water gage for 2 minutes.
Noncollapsibility	The hose shall not collapse or exhibit permanent deformation when a force of 90 kg. (200 pounds) is applied for 5 minutes between 2 planes 7.6 cm. (3 inches) wide on opposite sides of the hose.	Same as Type A	None.
Nonkinkability	None	None	A 7.6 m. (25 foot) section of the hose will be placed on a horizontal-plane surface and shaped into a one-loop coil with one end of the hose connected to an airflow meter and the other end of the hose supplied with air at the minimum specified supply pressure. The connection shall be in the plane of the loop. The other end of the hose will be pulled tangentially to the loop and in the plane of the loop until the hose straightens. To meet the requirements of this test the loop shall maintain a uniform near-circular shape and ultimately unfold as a spiral, without any localized deformation that decreases the flow of air to less than 90 percent of the flow when the hose is tested while remaining in a straight line.
Strength of hose and couplings.	Hose and couplings shall not separate or fail when tested with a pull of 113 kg. (250 pounds) for 5 minutes.	Same as Type A	Hose and couplings shall not exhibit any separation or failure when tested with a pull of 45 kg. (100 pounds) for 5 minutes and when tested by subjecting them to an internal air pressure of 2 times the maximum respirator-supply pressure that is specified by the applicant or at 173 kN/m. 2 (25 pounds per square inch) gage, whichever is higher.

TABLE 8—AIR-SUPPLY-LINE REQUIREMENTS AND TESTS—Continued
[42 CFR part 84, subpart J]

Specific requirements	Requirements for the air-supply lines of the indicated type of supplied-air respirators		
	Type A	Type B	Type C
Tightness	No air leakage shall occur when the hose and couplings are joined and the joint(s) are immersed in water and subjected to an internal air pressure of 35 kN/m. 2 (5 pounds per square inch) gage.	None	Leakage of air exceeding 50 cc. per minute at each coupling shall not be permitted when the hose and couplings are joined and are immersed in water, with air flowing through the respirator under a pressure of 173 kN/m. 2 (25 pounds per square inch) gage applied to the inlet end of the air-supply hose, or at twice the maximum respirator-supply pressure that is specified by the applicant, whichever is higher.
Permeation of hose by gasoline.	The permeation of the hose by gasoline will be tested by immersing 7.6 m. (25 feet) of hose and one coupling in gasoline, with air flowing through the hose at the rate of 8 liters per minute for 6 hours. The air from the hose shall not contain more than 0.01 percent by volume of gasoline vapor at the end of the test.	Same as for Type A	Same as for Type A, except the test period shall be 1 hour.
Detachable coupling	None	None	A hand-operated detachable coupling by which the wearer can readily attach or detach the connecting hose shall be provided at a convenient location. This coupling shall be durable, remain connected under all conditions of normal respirator use, and meet the prescribed tests for strength and tightness of hose and couplings.

Subpart K—Non-Powered Air-Purifying Particulate Respirators

§ 84.170 Non-powered air-purifying particulate respirators; description.

(a) Non-powered air-purifying particulate respirators utilize the wearer's negative inhalation pressure to draw the ambient air through the air-purifying filter elements (filters) to remove particulates from the ambient air. They are designed for use as respiratory protection against atmospheres with particulate contaminants (e.g., dusts, fumes, mists) that are not immediately dangerous to life or health and that contain adequate oxygen to support life.

(b) Non-powered air-purifying particulate respirators are classified into three series, N-, R-, and P-series. The N-series filters are restricted to use in those workplaces free of oil aerosols. The R- and P-series filters are intended for removal of any particulate that includes oil-based liquid particulates.

(c) Non-powered air-purifying particulate respirators are classified according to the efficiency level of the filter(s) as tested according to the requirements of this part.

(1) N100, R100, and P100 filters shall demonstrate a minimum efficiency level of 99.97 percent.

(2) N99, R99, and P99 filters shall demonstrate a minimum efficiency level of 99 percent.

(3) N95, R95, and P95 filters shall demonstrate a minimum efficiency level of 95 percent.

§ 84.171 Non-powered air-purifying particulate respirators; required components.

(a) Each non-powered air-purifying particulate respirator described in § 84.170 shall, where its design requires, contain the following component parts:

(1) Facepiece, mouthpiece with noseclip, hood, or helmet;
(2) Filter unit;
(3) Harness;
(4) Attached blower; and
(5) Breathing tube.

(b) The components of each non-powered air-purifying particulate respirator shall meet the minimum construction requirements set forth in subpart G of this part.

§ 84.172 Breathing tubes; minimum requirements.

Flexible breathing tubes used in conjunction with respirators shall be designed and constructed to prevent:

(a) Restriction of free head movement;

(b) Disturbance of the fit of facepieces, mouthpieces, hoods, or helmets;

(c) Interference with the wearer's activities; and

(d) Shutoff of airflow due to kinking, or from chin or arm pressure.

§ 84.173 Harnesses; installation and construction; minimum requirements.

(a) Each respirator shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearer's body.

(b) Harnesses shall be designed and constructed to permit easy removal and replacement of respirator parts, and, where applicable, provide for holding a full facepiece in the ready position when not in use.

§ 84.174 Respirator containers; minimum requirements.

(a) Except as provided in paragraph (b) of this section each respirator shall be equipped with a substantial, durable container bearing markings which show the applicant's name, the type of respirator it contains, and all appropriate approval labels.

(b) Containers for single-use respirators may provide for storage of more than one respirator, however, such containers shall be designed and constructed to prevent contamination of respirators which are not removed, and to prevent damage to respirators during transit.

§ 84.175 Half-mask facepieces, full facepieces, hoods, helmets, and mouthpieces; fit; minimum requirements.

(a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either:

(1) By providing more than one facepiece size; or

(2) By providing one facepiece size which will fit varying facial shapes and sizes.

(b) Full facepieces shall provide for optional use of corrective spectacles or lenses, which shall not reduce the respiratory protective qualities of the respirator.

(c) Hoods and helmets shall be designed and constructed to fit persons with various head sizes, provide for the optional use of corrective spectacles or lenses, and insure against any restriction of movement by the wearer.

(d) Mouthpieces shall be equipped with noseclips which are securely attached to the mouthpiece or respirator and provide an airtight seal.

(e) Facepieces, hoods, and helmets shall be designed to prevent eyepiece fogging.

(f) Half-mask facepieces shall not interfere with the fit of common industrial safety corrective spectacles.

§ 84.176 Facepieces, hoods, and helmets; eyepieces; minimum requirements.

Facepieces, hoods, and helmets shall be designed and constructed to provide adequate vision which is not distorted by the eyepieces.

§ 84.177 Inhalation and exhalation valves; minimum requirements.

(a) Inhalation and exhalation valves shall be protected against distortion.

(b) Inhalation valves shall be designed and constructed and provided where necessary to prevent excessive exhaled air from adversely affecting filters, except where filters are specifically designed to resist moisture.

(c) Exhalation valves shall be:

(1) Provided where necessary;

(2) Protected against damage and external influence; and

(3) Designed and constructed to prevent inward leakage of contaminated air.

§ 84.178 Head harnesses; minimum requirements.

(a) All facepieces shall be equipped with head harnesses designed and constructed to provide adequate tension during use and an even distribution of pressure over the entire area in contact with the face.

(b) Facepiece head harnesses, except those employed on single-use respirators, shall be adjustable and replaceable.

(c) Mouthpieces shall be equipped, where applicable, with adjustable and replaceable harnesses, designed and constructed to hold the mouthpiece in place.

§ 84.179 Non-powered air-purifying particulate respirators; filter identification.

(a) The respirator manufacturer, as part of the application for certification, shall specify the filter series and the filter efficiency level (i.e., "N95", "R95, "P95", "N99, "R99", "P99", "N100", "R100", or "P100") for which certification is being sought.

(b) Filters shall be prominently labeled as follows:

(1) N100 filters shall be labeled "N100 Particulate Filter (99.97% filter efficiency level)" and shall be a color other than magenta.

(2) R100 filters shall be labeled "R100 Particulate Filter (99.97% filter efficiency level)" and shall be a color other than magenta.

(3) P100 filters shall be labeled "P100 Particulate Filter (99.97% filter efficiency level)" and shall be color coded magenta.

(4) N99 filters shall be labeled "N99 Particulate Filter (99% filter efficiency level)" and shall be a color other than magenta.

(5) R99 filters shall be labeled "R99 Particulate Filter (99% filter efficiency level)" and shall be a color other than magenta.

(6) P99 filters shall be labeled "P99 Particulate Filter (99% filter efficiency level)" and shall be a color other than magenta.

(7) N95 filters shall be labeled as "N95 Particulate Filter (95% filter efficiency level)" and shall be a color other than magenta.

(8) R95 filters shall be labeled as "R95 Particulate Filter (95% filter efficiency level)" and shall be a color other than magenta.

(9) P95 filters shall be labeled as "P95 Particulate Filter (95% filter efficiency level)" and shall be a color other than magenta.

§ 84.180 Airflow resistance tests.

(a) Resistance to airflow will be measured in the facepiece, mouthpiece, hood, or helmet of a particulate respirator (complete respirator) mounted on a test fixture with air flowing at continuous rate of 85±2 liters per minute, before each test conducted in accordance with § 84.182.

(b) The resistances for particulate respirators upon initial inhalation shall not exceed 35 mm water column height pressure and upon initial exhalation shall not exceed 25 mm water column height pressure.

§ 84.181 Non-powered air-purifying particulate filter efficiency level determination.

(a) Twenty filters of each non-powered air-purifying particulate respirator model shall be tested for filter efficiency against:

(1) A solid sodium chloride particulate aerosol as per this section, if N-series certification is requested by the applicant.

(2) A dioctyl phthalate or equivalent liquid particulate aerosol as per this section, if R-series or P-series certification is requested by the applicant.

(b) Filters including holders and gaskets; when separable, shall be tested for filter efficiency level, as mounted on a test fixture in the manner as used on the respirator.

(c) Prior to filter efficiency testing of 20 N-series filters, the 20 to be tested shall be taken out of their packaging and placed in an environment of 85±5 percent relative humidity at 38±2.5 °C for 25±1 hours. Following the pre-conditioning, filters shall be sealed in a gas-tight container and tested within 10 hours.

(d) When the filters do not have separable holders and gaskets, the exhalation valves shall be blocked so as to ensure that leakage, if present, is not included in the filter efficiency level evaluation.

(e) For non-powered air-purifying particulate respirators with a single filter, filters shall be tested at a continuous airflow rate of 85±4 liters per minute. Where filters are to be used in pairs, the test-aerosol airflow rate shall be 42.5±2 liters per minute through each filter.

(f) *Filter efficiency test aerosols.* (1) When testing N-series filters, a sodium chloride or equivalent solid aerosol at 25±5 °C and relative humidity of 30±10 percent that has been neutralized to the Boltzmann equilibrium state shall be used. Each filter shall be challenged with a concentration not exceeding 200 mg/m^3.

(2) When testing R-series and P-series filters, a neat cold-nebulized dioctyl phthalate (DOP) or equivalent aerosol at 25±5 °C that has been neutralized to the Boltzmann equilibrium state shall be used. Each filter shall be challenged with a concentration not exceeding 200 mg/m^3.

(3) The test shall continue until minimum efficiency is achieved or until an aerosol mass of at least 200±5 mg has contacted the filter. For P-series filters, if the filter efficiency is decreasing when the 200±5 mg challenge point is reached, the test shall be continued until there is no further decrease in efficiency.

(g) The sodium chloride test aerosol shall have a particle size distribution with count median diameter of 0.075±0.020 micrometer and a standard geometric deviation not exceeding 1.86 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent. The DOP aerosol shall have a particle size distribution with count median diameter of 0.185±0.020 micrometer and a standard geometric deviation not exceeding 1.60 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.

(h) The efficiency of the filter shall be monitored and recorded throughout the test period by a suitable forward-light-scattering photometer or equivalent instrumentation.

(i) The minimum efficiency for each of the 20 filters shall be determined and recorded and be equal to or greater than the filter efficiency criterion listed for each level as follows:

P100, R100 and N100: Efficiency ≥99.97%
P99, R99 and N99: Efficiency ≥99%
P95, R95 and N95: Efficiency ≥95%

§ 84.182 Exhalation valve leakage test; minimum requirements.

(a) Dry exhalation valves and valve seats will be subjected to a suction of 25 mm. water-column height while in a normal operating position.

(b) Leakage between the valve and valve seat shall not exceed 30 milliliters per minute.

Subpart L—Chemical Cartridge Respirators

§ 84.190 Chemical cartridge respirators: description.

(a) Chemical cartridge respirators including all completely assembled respirators which are designed for use as respiratory protection during entry into or escape from atmospheres not immediately dangerous to life and health, are described according to the specific gases or vapors against which they are designed to provide respiratory protection, as follows:

Type of chemical cartridge respirator [1]	Maximum use concentration, parts per million
Ammonia	300
Chlorine	10
Hydrogen chloride	50
Methyl amine	100
Organic vapor	[2] 1,000
Sulfur dioxide	50
Vinyl chloride	10

[1] Not for use against gases or vapors with poor warning properties (except where MSHA or Occupational Safety and Health Administration standards may permit such use for a specific gas or vapor) or those which generate high heats of reaction with sorbent material in the cartridge.

[2] Maximum use concentrations are lower for organic vapors which produce atmospheres immediately hazardous to life or health at concentrations equal to or lower than this concentration.

(b) Chemical cartridge respirators for respiratory protection against gases or vapors, which are not specifically listed with their maximum use concentration, may be approved if the applicant

submits a request for such approval, in writing, to the Institute. The Institute shall consider each such application and accept or reject the application after a review of the effects on the wearer's health and safety and in the light of any field experience in use of chemical cartridge respirators as protection against such hazards.

§ 84.191 Chemical cartridge respirators; required components.

(a) Each chemical cartridge respirator described in § 84.190 shall, where its design requires, contain the following component parts:

(1) Facepiece, mouthpiece, and noseclip, hood, or helmet;

(2) Cartridge;

(3) Cartridge with filter;

(4) Harness;

(5) Breathing tube; and

(6) Attached blower.

(b) The components of each chemical cartridge respirator shall meet the minimum construction requirements set forth in subpart G of this part.

§ 84.192 Cartridges in parallel; resistance requirements.

Where two or more cartridges are used in parallel, their resistance to airflow shall be essentially equal.

§ 84.193 Cartridges; color and markings; requirements.

The color and markings of all cartridges or labels shall conform with the requirements of the American National Standards Institute, American National Standard for Identification of Air-Purifying Respirator Canisters and Cartridges, ANSI K13.1–1973. ANSI K13.1 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018. Copies may be inspected at the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

§ 84.194 Filters used with chemical cartridges; location; replacement.

(a) Particulate matter filters used in conjunction with a chemical cartridge shall be located on the inlet side of the cartridge.

(b) Filters shall be incorporated in or firmly attached to the cartridge and each filter assembly shall, where applicable, be designed to permit its easy removal from and replacement on the cartridge.

§ 84.195 Breathing tubes; minimum requirements.

Flexible breathing tubes used in conjunction with respirators shall be designed and constructed to prevent:

(a) Restriction of free head movement;

(b) Disturbance of the fit of facepieces, mouthpieces, hoods, or helmets;

(c) Interference with the wearer's activities; and

(d) Shutoff of airflow due to kinking, or from chin or arm pressure.

§ 84.196 Harnesses; installation and construction; minimum requirements.

(a) Each respirator shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearer's body.

(b) Harnesses shall be designed and constructed to permit easy removal and replacement of respirator parts and, where applicable, provide for holding a full facepiece in the ready position when not in use.

§ 84.197 Respirator containers; minimum requirements.

Respirators shall be equipped with a substantial, durable container bearing markings which show the applicant's name, the type and commercial designation of the respirator it contains and all appropriate approval labels.

§ 84.198 Half-mask facepieces, full facepieces, mouthpieces, hoods, and helmets; fit; minimum requirements.

(a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either:

(1) By providing more than one facepiece size; or

(2) By providing one facepiece size which will fit varying facial shapes and sizes.

(b) Hoods and helmets shall be designed and constructed to fit persons with various head sizes, provide for the optional use of corrective spectacles or lenses, and insure against any restriction of movement by the wearer.

(c) Mouthpieces shall be equipped with noseclips which are securely attached to the mouthpiece or respirator and provide an airtight fit.

(d) Full facepieces shall provide for optional use of corrective spectacles or lenses which shall not reduce the respiratory protective qualities of the respirator.

(e) Facepieces, hoods, and helmets shall be designed to prevent eyepiece fogging.

§ 84.199 Facepieces, hoods, and helmets; eyepieces; minimum requirements.

Facepieces, hoods, and helmets shall be designed and constructed to provide adequate vision which is not distorted by the eyepieces.

§ 84.200 Inhalation and exhalation valves; minimum requirements.

(a) Inhalation and exhalation valves shall be provided where necessary and protected against distortion.

(b) Inhalation valves shall be designed and constructed to prevent excessive exhaled air from entering cartridges or adversely affecting canisters.

(c) Exhalation valves shall be—

(1) Protected against damage and external influence; and

(2) Designed and constructed to prevent inward leakage of contaminated air.

§ 84.201 Head harnesses; minimum requirements.

(a)(1) Facepieces for chemical cartridge respirators other than single-use vinyl chloride shall be equipped with adjustable and replaceable head harnesses designed and constructed to provide adequate tension during use and an even distribution of pressure over the entire area in contact with the face.

(2) Facepieces for single-use vinyl chloride respirators shall be equipped with adjustable head harnesses designed and constructed to provide adequate tension during use and an even distribution of pressure over the entire area in contact with the face.

(b) Mouthpieces shall be equipped where applicable, with an adjustable and replaceable harness designed and constructed to hold the mouthpiece in place.

§ 84.202 Air velocity and noise levels; hoods and helmets; minimum requirements.

Noise levels generated by the respirator will be measured inside the hood or helmet at maximum airflow obtainable and shall not exceed 80 dBA.

§ 84.203 Breathing resistance test; minimum requirements.

(a) Resistance to airflow will be measured in the facepiece, mouthpiece, hood, or helmet of a chemical cartridge respirator mounted on a test fixture with air flowing at a continuous rate of 85 liters per minute, both before and after each test conducted in accordance with §§ 84.206 through 84.207.

(b) The maximum allowable resistance requirements for chemical cartridge respirators are as follows:

MAXIMUM RESISTANCE

[Millimeter water column height]

Type of chemical-cartridge respirator	Inhalation		Exhalation
	Initial	Final[1]	
Other than single-use vinyl chloride respirators:			
For gases, vapors, or gases and vapors	40	45	20

MAXIMUM RESISTANCE—Continued
[Millimeter water column height]

Type of chemical-cartridge respirator	Inhalation		Exhalation
	Initial	Final[1]	
For gases, vapors, or gases and vapors, and particulates	50	70	20
Single-use respirator with valves:			
For vinyl chloride	20	25	20
For vinyl chloride and particulates	30	45	2
Single-use respirator without valves:			
For vinyl chloride	15	20	[2]
For vinyl chloride and particulates	25	40	[2]

[1] Measured at end of service life specified in Table 11 of this subpart.
[2] Same as inhalation.

§ 84.204 Exhalation valve leakage test; minimum requirements.

(a) Dry exhalation valves and valve seats will be subjected to a suction of 25 mm. water-column height while in a normal operating position.

(b) Leakage between the valve and valve seat shall not exceed 30 milliliters per minute.

§ 84.205 Facepiece test; minimum requirements.

(a) The complete chemical cartridge respirator will be fitted to the faces of persons having varying facial shapes and sizes.

(b) Where the applicant specifies a facepiece size or sizes for the respirator together with the approximate measurement of faces they are designed to fit, the Institute will provide test subjects to suit such facial measurements.

(c) Any chemical cartridge respirator part which must be removed to perform the facepiece or mouthpiece fit test shall be replaceable without special tools and without disturbing facepiece or mouthpiece fit.

(d) The facepiece or mouthpiece fit test using the positive or negative pressure recommended by the applicant and described in his instructions will be used before each test.

(e)(1) Each wearer will enter a chamber containing 100 p.p.m. isoamyl acetate vapor for half-mask facepieces, and 1,000 p.p.m. for full facepieces, mouthpieces, hoods, and helmets.

(2) The facepiece or mouthpiece may be adjusted, if necessary, in the test chamber before starting the test.

(3) Each wearer will remain in the chamber for 8 minutes while performing the following activities:

(i) Two minutes, nodding and turning head;

(ii) Two minutes, calisthenic arm movements;

(iii) Two minutes, running in place; and

(iv) Two minutes, pumping with a tire pump into a 28-liter (1 cubic-foot) container.

(4) Each wearer shall not detect the odor of isoamyl-acetate vapor during the test.

§ 84.206 Particulate tests; respirators with filters; minimum requirements; general.

(a) Three respirators with cartridges containing, or having attached to them, filters for protection against particulates will be tested in accordance with the provisions of § 84.207.

(b) In addition to the test requirements set forth in paragraph (a) of this section, three such respirators will be tested, as appropriate, in accordance with the provisions of §§ 84.179 through 84.183; however, the maximum allowable resistance of complete particulate, and gas, vapor, or gas and vapor chemical cartridge respirators shall not exceed the maximum allowable limits set forth in § 84.203.

§ 84.207 Bench tests; gas and vapor tests; minimum requirements; general.

(a) Bench tests will be made on an apparatus that allows the test atmosphere at 50±5 percent relative humidity and room temperature, approximately 25 °C, to enter the cartridges continuously at predetermined concentrations and rates of flow, and that has means

for determining the test life of the cartridges.

(b) Where two cartridges are used in parallel on a chemical cartridge respirator, the bench test will be performed with the cartridges arranged in parallel, and the test requirements will apply to the combination rather than to the individual cartridges.

(c) Three cartridges or pairs of cartridges will be removed from containers and tested as received from the applicant.

(d) Two air purifying cartridges or pairs of cartridges will be equilibrated at room temperature by passing 25 percent relative humidity air through them at the flow rate of 25 liters per minute (l.p.m.) for 6 hours.

(e) Two air purifying cartridges or pairs of cartridges will be equilibrated by passing 85 percent relative humidity air through them at the flow rate of 25 l.p.m.

(f) All cartridges will be resealed, kept in an upright position, at room temperatures, and tested within 18 hours.

(g) Cartridges will be tested and shall meet the minimum requirements set forth in Table 11 of this subpart.

TABLES TO SUBPART L OF PART 84

TABLES 9–10 [RESERVED]

TABLE 11—CARTRIDGE BENCH TESTS AND REQUIREMENTS

[42 CFR part 84, subpart L]

Cartridge	Test condition	Test atmosphere		Flowrate (l.p.m.)	Number of tests	Penetration [1] (p.p.m.)	Minimum life [2] (min.)
		Gas or vapor	Concentration (p.p.m.)				
Ammonia	As received	NH_3	1000	64	3	50	50
Ammonia	Equilibrated	NH_3	1000	32	4	50	50
Chlorine	As received	Cl_2	500	64	3	5	35
Chlorine	Equilibrated	Cl_2	500	32	4	5	35
Hydrogen chloride.	As received	HCl	500	64	3	5	50
Hydrogen chloride.	Equilibrated	HCl	500	32	4	5	50
Methylamine	As received	$CH_3\ NH_2$	1000	64	3	10	25
Methylamine	Equilibrated	$CH_3\ NH_2$	1000	32	4	10	25
Organic vapors ..	As received	CCl_4	1000	64	3	5	50
Organic vapors ..	Equilibrated	CCl_4	1000	32	4	5	50
Sulfur dioxide	As received	SO_2	500	64	3	5	30
Sulfur dioxide	Equilibrated	SO_2	500	32	4	5	30

[1] Minimum life will be determined at the indicated penetration.

[2] Where a respirator is designed for respiratory protection against more than one type of gas or vapor, as for use in ammonia and in chlorine, the minimum life shall be one-half that shown for each type of gas or vapor. Where a respirator is designed for respiratory protection against more than one gas of a type, as for use in chlorine and sulfur dioxide, the stated minimal life shall apply.

Subpart M [Reserved]

Subpart N—Special Use Respirators

§ 84.250 Vinyl chloride respirators; description.

Vinyl chloride respirators, including all completely assembled respirators which are designed for use as respiratory protection during entry into and escape from vinyl chloride atmospheres containing adequate oxygen to support life, are described according to their construction as follows:

(a) Front-mounted or back-mounted gas masks;

(b) Chin-style gas masks;

(c) Chemical-cartridge respirators;

(d) Powered air-purifying respirators; and

(e) Other devices, including combination respirators.

§ 84.251 Required components.

(a) Each vinyl chloride respirator described in § 84.250 shall, where its design requires, contain the following component parts:

(1) Facepiece;

(2) Canister with end-of-service-life indicator;

(3) Cartridge with end-of-service-life indicator;

(4) Harness;

(5) Attached blower; and

(6) Breathing tube.

(b) The components of each vinyl chloride respirator shall meet the minimum construction requirements set forth in Subpart G of this part.

§ 84.252 Gas masks; requirements and tests.

(a) Except for the tests prescribed in § 84.126, the minimum requirements and performance tests for gas masks, prescribed in Subpart I of this part, are applicable to vinyl chloride gas masks.

(b) The following bench tests are applicable to canisters designed for use with gas masks for entry into and escape from vinyl chloride atmospheres containing adequate oxygen to support life:

(1) Four canisters will be equilibrated at 25±5 °C by passing 85±5 percent relative humidity air through them at 64 liters per minute for six hours.

(2) The equilibrated canisters will be resealed, kept in an upright position at room temperature, and tested according to paragraph (b)(3) of this section within 18 hours.

(3) The canisters equilibrated and stored as described in paragraphs (b) (1) and (2) of this section will be tested on an apparatus that allows the test atmosphere at 85±5 percent relative humidity and 25±5 °C to enter the canister continuously at a concentration of 25 ppm vinyl chloride monomer at a total flow rate of 64 liters per minute.

(4) The maximum allowable penetration after six hours of testing according to paragraph (b)(3) of this section shall not exceed 1 ppm vinyl chloride.

(c) Where canisters are submitted for testing and approval with a service life of more than four hours, the period of time for testing for vinyl chloride penetration will be performed at 150% of the service life specified in the manufacturer's application. (Example: If a manufacturer requests approval of a respirator for six hours use against exposure to vinyl chloride, the maximum allowable penetration after nine hours of testing shall not exceed 1 ppm vinyl chloride.)

§ 84.253 Chemical-cartridge respirators; requirements and tests.

(a) Except for the tests prescribed in §§ 84.206 and 84.207, the minimum requirements and performance tests for chemical-cartridge respirators prescribed in Subpart L of this part are applicable to replaceable-cartridge and single-use vinyl chloride chemical-cartridge respirators.

(b) The following bench tests are applicable to cartridges designed for use with chemical-cartridge respirators for entry into and escape from vinyl chloride atmospheres containing adequate oxygen to support life:

(1) Where two cartridges are used in parallel on a chemical-cartridge respirator, the bench test requirements will apply to the combination rather than the individual cartridges.

(2) Four cartridges or pairs of cartridges will be equilibrated at 25±5 °C by passing 85±5 percent relative humidity air through them at 25 liters per minute for six hours.

(3) The equilibrated cartridges will be resealed, kept in an upright position, at room temperature, and tested according to paragraphs (b)(4) and (b)(5) of this section for other than single-use respirators or according to paragraphs (b)(6) and (b)(7) of this section for single-use respirators within 18 hours.

(4) The cartridges or pairs of cartridges for other than single-use respirators, equilibrated and stored as described in paragraphs (b)(1), (b)(2), and (b)(3) of this section, will be tested on an apparatus that allows the test atmosphere at 85±5 percent relative humidity and 25±5 °C, to enter the cartridges or pairs of cartridges continuously at a concentration of 10 ppm vinyl chloride monomer at a total flowrate of 64 liters per minute.

(5) The maximum allowable penetration after 90 minutes testing of cartridges or pairs of cartridges for other than single-use respirators, according

to paragraph (b)(4) of this section shall not exceed 1 ppm vinyl chloride.

(6) The single-use respirators, equilibrated and stored as described in paragraphs (b)(2) and (b)(3) of this section, will be tested on an apparatus that allows a test atmosphere at 85±5 percent relative humidity and 25±5 °C to be cycled through the respirator by a breathing machine at a concentration of 10 ppm vinyl chloride monomer at the rate of 24 respirations per minute at a minute volume of 40±0.6 liters. Air exhaled through the respirator will be 35±2 °C with 94±3 percent relative humidity.

(7) The maximum allowable penetration after 144 minutes testing of respirators, according to paragraph (b)(6) of this section, shall not exceed 1 ppm vinyl chloride.

§ 84.254 Powered air-purifying respirators; requirements and tests.

(a) Except for the tests prescribed in § 84.207, the minimum requirements and performance tests for powered air-purifying respirators prescribed in subpart L of this part are applicable to vinyl chloride powered air-purifying respirators.

(b) The following bench tests are applicable to cartridges designed for use with powered air-purifying respirators for entry into and escape from vinyl chloride atmospheres containing adequate oxygen to support life:

(1) Four cartridges will be equilibrated at 25± °C by passing 85±5 percent relative humidity air through them at 115 liters per minute for tight-fitting facepieces and 170 liters per minute for loose-fitting hoods and helmets, for six hours.

(2) The equilibrated cartridges will be resealed, kept in an upright position at room temperature and tested according to paragraph (b)(3) of this section within 18 hours.

(3) The cartridges equilibrated and stored as described in paragraphs (b) (1) and (2) of this section will be tested on an apparatus that allows the test atmosphere at 85±5 percent relative humidity and 25±5 °C to enter the cartridge continuously at a concentration of 25 ppm vinyl chloride monomer at a total flow rate of 115 liters per minute for tight-fitting facepieces and 170 liters per minute for loose-fitting hoods and helmets.

(4) The maximum allowable penetration after six hours of testing according to paragraph (b)(3) of this section shall not exceed 1 ppm vinyl chloride.

§ 84.255 Requirements for end-of-service-life indicator.

(a) Each canister or cartridge submitted for testing and approval in accordance with §§ 84.252, 84.253, and 84.254 shall be equipped with a canister or cartridge end-of-service-life indicator which shows a satisfactory indicator change or other obvious warning before 1 ppm vinyl chloride penetration occurs. The indicator shall show such change or afford such warning at 80±10 percent of the total service life to 1 ppm leakage, as determined by continuing each test described in §§ 84.252(b), 84.253(b), and 84.254(b) until a 1 ppm leakage of vinyl chloride occurs.

(b) The applicant shall provide sufficient pretest data to verify the performance of the end-of-service-life indicator required in paragraph (a) of this section.

§ 84.256 Quality control requirements.

(a) In addition to the construction and performance requirements specified in §§ 84.251, 84.252, 84.253, 84.254, and 84.255, the quality control requirements in paragraphs (b), (c), and (d) of this section apply to approval of gas masks, chemical cartridge respirators, and powered air-purifying respirators for entry into and escape from vinyl chloride atmospheres containing adequate oxygen to support life.

(b) The respirators submitted for approval as described in paragraph (a) of this section shall be accompanied by a complete quality control plan meeting the requirements of subpart E of this part.

(c)(1) The applicant shall specify in the plan that a sufficient number of samples will be drawn from each bulk container of sorbent material and that where activated carbon is used, the following specific tests will be performed:

(i) Apparent density;

(ii) Iodine number;

(iii) Moisture content;

(iv) Carbon tetrachloride number; and

(v) Mesh size.

(2) The tests in paragraph (c)(1) of this section shall be performed in a quantity necessary to assure continued satisfactory conformance of the canisters and cartridges to the requirements of this subpart.

(d) Final performance quality control tests on the complete canisters and cartridges shall be accomplished using the bench tests and procedures prescribed in §§84.252, 84.253, 84.254, and 84.255.

§ 84.257 Labeling requirements.

(a) A warning shall be placed on the label of each gas mask, chemical-cartridge respirator, and powered air-purifying respirator, and on the label of each canister and cartridge, alerting the wearer to the need for a fitting test in accordance with the manufacturer's facepiece fitting instructions, providing service life information, providing specific instructions for disposal, and advising that the wearer may communicate to NIOSH any difficulties that may be experienced in the design and performance of any gas mask, chemical-cartridge respirator, or powered air-purifying respirator approved under the requirements of this subpart. The service lives of respirators meeting the test requirements of this subpart shall be specified as follows:

Chemical-cartridge respirator	1 hour.
Gas mask	4 hours.
Powered air-purifying respirator	4 hours.

(b) Where the service life of a respirator is approved for more than four hours, the service life for which the respirator has been approved will be specified.

§ 84.258 Fees.

The following fees shall be charged for the examination, inspection, and testing of complete assemblies and components of respirators described in §§84.250 and 84.251:

Complete gas mask	$1,100
Complete chemical-cartridge respirator	1,150
Complete powered air-purifying respirator	1,500
Canister or cartridge only	750

Subparts O–JJ [Reserved]

Subpart KK—Dust, Fume, and Mist; Pesticide; Paint Spray; Powered Air-Purifying High Efficiency Respirators and Combination Gas Masks

§ 84.1100 Scope and effective dates.

The purpose of this subpart KK is to establish procedures and requirements for issuing extensions of approval of particulate respirators certified prior to July 10, 1995 under the provisions of 30 CFR part 11 (See 30 CFR part 11 edition, as revised July 1, 1994.), new approvals and extensions of approval of particulate respirators for applications that are in NIOSH receipt on July 10, 1995, and approval of powered air-purifying respirators.

(a) Air-purifying respirators with particulate filters approved under the provisions of this subpart after July 10, 1995 will have a 30 CFR part 11 approval label.

(b) Only changes or modifications of non-powered air-purifying respirators with particulate filters approved under the provisions of subparts I, K, L, or M of 30 CFR part 11 or paragraph (a) of this section and deemed necessary by NIOSH to ensure the health and safety of the wearer will be approved until July 10, 1998 and will have a 30 CFR part 11 approval label.

(c) Only changes or modifications of powered air-purifying respirators with particulate filters approved under the provisions of subparts I, K, L, or M of 30 CFR part 11 or paragraph (a) of this section and deemed necessary by NIOSH to ensure the health and safety of the wearer will be approved under this subpart until July 10, 1998 and will have a 30 CFR part 11 label.

(d) Approval of powered air-purifying respirators will be issued under this subpart. Particulate filters for powered air-purifying respirators approved under the provisions of this subpart shall be only high-efficiency (HEPA) as described in §84.1130(a)(4) and will carry a 42 CFR part 84 approval label. In addition, changes or modifications of powered HEPA air-purifying respirators approved under the provisions of this subpart KK will be approved

under this subpart and will have a 42 CFR part 84 approval label.

§ 84.1101 Definitions.

As used in this subpart

(a) *Air Contamination Level* means the standards of contaminant levels prescribed by the Secretary of Labor in accordance with the provisions of the Occupational Safety and Health Act of 1970 (Pub. L. 91–596; 84 Stat. 1590).

(b) *DOP* means a homogenous liquid aerosol, having a particle diameter of 0.3 micrometer, which is generated by vaporization and condensation of dioctyl phthalate.

(c) *Pesticide* means:

(1) Any substance or mixture of substances (including solvents and impurities) intended to prevent, destroy, repel, or mitigate any insect, rodent, nematode, fungus, weed, or other form of plant or animal life or virus; and

(2) Any substance or mixture of substances (including solvents and impurities) intended for use as a plant regulator, defoliant, or desiccant, as defined in the Federal Insecticide, Fungicide, and Rodenticide Act of 1947, as amended (7 U.S.C. 135–135k), excluding fumigants which are applied as gases or vapors or in a solid or liquid form as pellets or poured liquids for subsequent release as gases or vapors.

(d) *Radionuclide* means an atom identified by the constitution of its nucleus (specified by the number of protons Z, number of neutrons N, and energy, or, alternatively, by the atomic number Z, mass number A=(N+Z), and atomic mass) which exists for a measurable time; decays or disintegrates spontaneously, emits radiation, and results in the formation of new nuclides.

(e) *Smoke* means the products of incomplete combustion of organic substances in the form of solid and liquid particles and gaseous products in air, usually of sufficient concentration to perceptibility obscure vision.

§ 84.1102 Examination, inspection and testing of complete respirator assemblies; fees.

The following fees shall be charged by the Institute for the examination, inspection and testing of complete respirator assemblies approved under this subpart:

(a) Gas masks with particulate filter, including pesticide gas masks—

(1) Single hazard—$1,100.

(2) Type N—$4,100.

(b) Dust, fume and mist respirators—

(1) Single particulate hazard having an Air Contamination Level more than 0.05 mg./m.^{3} or 2 million particles per cubic foot—$500.

(2) Combination particulate hazards having an Air Contamination Level more than 0.05 mg./m.^{3} or 2 million particles per cubic foot—$750.

(3) Particulate hazards having an Air Contamination Level less than 0.05 mg./m.^{3} or 2 million particles per cubic foot, radon daughters —$1,250.

(4) All dusts, fumes and mists—$2,000.

(c) Paint spray respirators—$1,600.

(d) Pesticide respirators—$1,600.

(e) Chemical cartridge respirators with particulate filter—$1,150.

§ 84.1103 Approval labels and markings; approval of contents; use.

(a) Full-scale reproductions of approval labels and markings, and a sketch or description of the method of application and position on the harness, container, canister, cartridge, filter, or other component, together with instructions for the use and maintenance of the respirator shall be submitted to MSHA and the Institute for approval.

(b) Approval labels for non-powered and powered air-purifying dust, fume, mist respirators approved prior to July 10, 1995 under the provisions of subpart K of 30 CFR part 11 (See 30 CFR Part 11 edition, revised as of July 1, 1994.) shall bear the emblem of the Mine Safety and Health Administration and the seal of the Department of Health and Human Services, the applicant's name and address, an approval number assigned by the Institute, a statement that the respirator was tested and approved under subpart K of 30 CFR part 11 and, where appropriate, restrictions or limitations placed upon the use of the respirator by the Institute. The approval number assigned by the Institute shall be designated by the prefix TC and a serial number.

(c) Approval labels for powered air-purifying respirators approved under the provisions of this subpart shall

bear the emblem of the National Institute for Occupational Safety and Health and the seal of the Department of Health and Human Services, the applicant's name and address, an approval number assigned by the Institute, a statement stating the respirator was tested under the provisions of this subpart, and, where appropriate, restrictions or limitations placed upon the use of the respirator by the Institute. The approval number assigned by the Institute shall be designated by the prefix TC and a serial number.

(c) The Institute shall, where necessary, notify the applicant when additional labels, markings, or instructions will be required.

(d) Approval labels and markings shall only be used by the applicant to whom they were issued.

(e) Legible reproductions or abbreviated forms of the label approved by the Institute for use on each respirator shall be attached to or printed at the following locations:

Respirator type	Label type	Location
Gas mask with a particulate filter, including pesticide gas mask.	Entire	Mask and container.
Dust, fume, and mist respirators	Entire	Respirator container and filter container.
	Abbreviated	Filters.
Chemical-cartridge respirator with a particulate filter, including paint spray respirator.	Entire	Respirator container, cartridge container, and filter containers (where applicable).
	Abbreviated	Cartridges and filters and filter containers.
Pesticide respirator	Entire	Respirator container, and cartridge and filter containers.
	Abbreviated	Cartridges and filters.

(f) The use of any MSHA and Institute approval label obligates the applicant to whom it is issued to maintain or cause to be maintained the approved quality control sampling schedule and the acceptable quality level for each characteristic tested, and to assure that it is manufactured according to the drawings and specifications upon which the certificate of approval is based.

(g) Each respirator, respirator component, and respirator container shall, as required by the Institute to assure quality control and proper use of the respirator, be labeled distinctly to show the name of the applicant, and the name and letters or numbers by which the respirator or respirator component is designated for trade purposes, and the lot number, serial number, or approximate date of manufacture.

EDITORIAL NOTE: At 60 FR 30388, June 8, 1995, §84.1103 was added with two paragraph (c) designations.

§ 84.1130 Respirators; description.

(a) Dust, fume, and mist respirators, including all completely assembled respirators designed for use as respiratory protection during entry into and escape from atmospheres which contain adequate oxygen to support life and hazardous particulates, are described as follows:

(1) Air-purifying respirators, either with replaceable or reusable filters, designed as respiratory protection against dusts:

(i) Having an air contamination level not less than 0.05 milligram per cubic meter of air, including but not limited to coal, arsenic, cadmium, chromium, lead, and manganese; or

(ii) Having an air contamination level not less than 2 million particles per cubic foot of air, including but not limited to aluminum, flour, iron ore, and free silica, resulting principally from the disintegration of a solid, e.g., dust clouds produced in mining, quarrying, and tunneling, and in dusts produced during industrial operations, such as grinding, crushing, and the general processing of minerals and other materials.

(2) Air-purifying respirators, with replaceable filters, designed as respiratory protection against fumes of various metals having an air contamination level not less than 0.05 milligram per cubic meter, including but not limited to aluminum, antimony, arsenic, cadmium, chromium, copper,

iron, lead, magnesium, manganese, mercury (except mercury vapor), and zinc, which result from the sublimation or condensation of their respective vapors, or from the chemical reaction between their respective vapors and gases.

(3) Air-purifying respirators, with replaceable filters, designed as respiratory protection against mists of materials having an air contamination level not less than 0.05 milligram per cubic meter or 2 million particles per cubic foot, e.g., mists produced by spray coating with vitreous enamels, chromic acid mist produced during chromium plating, and other mists of materials whose liquid vehicle does not produce harmful gases or vapors.

(4) Air-purifying respirators, with replaceable filters, designed as respiratory protection against dusts, fumes, and mists having an air contamination level less than 0.05 milligram per cubic meter, including but not limited to lithium hydride and beryllium, and against radionuclides.

(5) Air-purifying respirators, with replaceable filters, designed as respiratory protection against radon daughters, and radon daughters attached to dusts, fumes, and mists.

(6) Air-purifying respirators, with replaceable filters, designed as respiratory protection against asbestos-containing dusts and mists.

(7) Air-purifying respirators, with replaceable filters, designed as protection against various combinations of particulate matter.

(8) Air-purifying dust respirators designed as respiratory protection against pneumoconiosis- and fibrosis-producing dusts, or dusts and mists, including but not limited to aluminum, asbestos, coal, flour, iron ore, and free silica.

(b) Gas masks containing filters for protection against dusts, fumes, mists, and smokes in combination with gases, vapors, or gases and vapors. These respirators are not for use against gases or vapors with poor warning properties (except where MSHA or Occupational Safety and Health Administration standards may permit such use for a specific gas or vapor) or those which generate high heats of reaction with sorbent material in the canister.

(c) Pesticide respirators, including all completely assembled respirators which are designed for use as respiratory protection during entry into and escape from atmospheres which contain pesticide hazards, are described according to their construction as follows:

(1) Front-mounted or back-mounted gas masks;

(2) Chin-style gas mask;

(3) Chemical cartridge;

(4) Air-purifying respirator with attached blower; and,

(5) Other devices, including combination respirators.

(d) Respirators with cartridges containing or having attached to them, filters for protection against mists of paints, lacquers, and enamels. These respirators are not for use against gases or vapors with poor warning properties (except where MSHA or Occupational Safety and Health Administration standards may permit such use for a specific gas or vapor) or those which generate high heats of reaction with sorbent material in the cartridge.

(e) Respirators with cartridges containing or having attached to them filters for protection against dusts, fumes, and mists, except the mists of paints, lacquers, and enamels. These respirators are not for use against gases or vapors with poor warning properties (except where MSHA or Occupational Safety and Health Administration standards may permit such use for a specific gas or vapor) or those which generate high heats of reaction with sorbent material in the cartridge.

§84.1131 Respirators; required components.

(a) Each respirator described in §84.1130 shall, where its design requires, contain the following component parts:

(1) Facepiece, mouthpiece with noseclip, hood, or helmet;

(2) Filter unit, canister with filter, or cartridge with filter;

(3) Harness;

(4) Attached blower; and

(5) Breathing tube.

(b) The components of each respirator shall meet the minimum construction requirements set forth in Subpart G of this part.

§ 84.1132 Breathing tubes; minimum requirements.

(a) Flexible breathing tubes used in conjunction with respirators shall be designed and constructed to prevent:

(1) Restriction of free head movement;

(2) Disturbance of the fit of facepieces, mouthpieces, hoods, or helmets;

(3) Interference with the wearer's activities; and

(4) Shutoff of airflow due to kinking, or from chin or arm pressure.

§ 84.1133 Harnesses; installation and construction; minimum requirements.

(a) Each respirator shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearer's body.

(b) Harnesses shall be designed and constructed to permit easy removal and replacement of respirator parts, and, where applicable, provide for holding a full facepiece in the ready position when not in use.

§ 84.1134 Respirator containers; minimum requirements.

(a) Except as provided in paragraph (b) of this section each respirator shall be equipped with a substantial, durable container bearing markings which show the applicant's name, the type of respirator it contains, and all appropriate approval labels. Except for dust, fume, and mist respirators, the commercial designation of the respirator it contains shall be shown.

(b) Containers for single-use respirators may provide for storage of more than one respirator, however, such containers shall be designed and constructed to prevent contamination of respirators which are not removed, and to prevent damage to respirators during transit.

(c) Containers for gas masks combinations shall be designed and constructed to permit easy removal of the mask.

§ 84.1135 Half-mask facepieces, full facepieces, hoods, helmets, and mouthpieces; fit; minimum requirements.

(a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either:

(1) By providing more than one facepiece size; or

(2) By providing one facepiece size which will fit varying facial shapes and sizes.

(b) Full facepieces shall provide for optional use of corrective spectacles or lenses, which shall not reduce the respiratory protective qualities of the respirator.

(c) Hoods and helmets shall be designed and constructed to fit persons with various head sizes, provide for the optional use of corrective spectacles or lenses, and insure against any restriction of movement by the wearer.

(d) Mouthpieces shall be equipped with noseclips which are securely attached to the mouthpiece or respirator and provide an airtight seal.

(e) Facepieces, hoods, and helmets shall be designed to prevent eyepiece fogging.

(f) Half-mask facepieces shall not interfere with the fit of common industrial safety corrective spectacles, as determined by the Institute's facepiece tests in §§ 84.1141, 84.1142, and 84.1156(b).

§ 84.1136 Facepieces, hoods, and helmets; eyepieces; minimum requirements.

(a) Facepieces, hoods, and helmets shall be designed and constructed to provide adequate vision which is not distorted by the eyepieces.

(b) All eyepieces of gas masks combinations shall be designed and constructed to be impact and penetration resistant. Federal Specification, Mask, Air Line: and Respirator, Air Filtering, Industrial, GGG–M–125d, October 11, 1965, with interim amendment-1, July 30, 1969, is an example of an appropriate standard for determining impact and penetration resistance. Copies of GGG–M–125d may be obtained from the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888.

§ 84.1137 Inhalation and exhalation valves; minimum requirements.

(a) Inhalation and exhalation valves shall be protected against distortion.

(b) Inhalation valves shall be designed and constructed and provided where necessary to prevent excessive exhaled air from adversely affecting filters, cartridges, and canisters, except where filters of dust, fume, and mist respirators are specifically designed to resist moisture as prescribed in § 84.1145.

(c) Exhalation valves shall be:

(1) Provided where necessary;

(2) Protected against damage and external influence; and

(3) Designed and constructed to prevent inward leakage of contaminated air.

§ 84.1138 Head harnesses; minimum requirements.

(a) All facepieces shall be equipped with head harnesses designed and constructed to provide adequate tension during use and an even distribution of pressure over the entire area in contact with the face.

(b) Facepiece head harnesses, except those employed on single-use dust, fume, and mist respirators, shall be adjustable and replaceable.

(c) Mouthpieces shall be equipped, where applicable, with adjustable and replaceable harnesses, designed and constructed to hold the mouthpiece in place.

§ 84.1139 Air velocity and noise levels; hoods and helmets; minimum requirements.

Noise levels generated by the respirator will be measured inside the hood or helmet at maximum airflow obtainable and shall not exceed 80 dBA.

§ 84.1140 Dust, fume, and mist respirators; performance requirements; general.

Dust, fume, and mist respirators and the individual components of each such device shall, as appropriate, meet the requirements for performance and protection specified in the tests described in §§ 84.1141 through 84.1152 and prescribed in Tables 12 and 13.

§ 84.1141 Isoamyl acetate tightness test; dust, fume, and mist respirators designed for respiratory protection against fumes of various metals having an air contamination level not less than 0.05 milligram per cubic meter; minimum requirements.

(a) The respirator will be modified in such a manner that all of the air that normally would be inhaled through the inhalation port(s) is drawn through an efficient activated charcoal-filled canister, or cartridge(s), without interference with the face-contacting portion of the facepiece.

(b) The modified respirator will be worn by persons for at least 2 minutes each in a test chamber containing 100 parts (by volume) of isoamyl-acetate vapor per million parts of air.

(c) The odor of isoamyl-acetate shall not be detected by the wearers of the modified respirator while in the test atmosphere.

§ 84.1142 Isoamyl acetate tightness test; respirators designed for respiratory protection against dusts, fumes, and mists having an air contamination level less than 0.05 milligram per cubic meter, or against radionuclides; minimum requirements.

(a) The applicant shall provide a charcoal-filled canister or cartridge of a size and resistance similar to the filter unit with connectors which can be attached to the facepiece in the same manner as the filter unit.

(b)(1) The canister or cartridge will be used in place of the filter unit, and persons will each wear a modified half-mask facepiece for 5 minutes in a test chamber containing 100 parts (by volume) of isoamyl-acetate vapor per million parts of air.

(2) The following work schedule will be performed by each wearer in the test chamber:

(i) Two minutes walking, nodding, and shaking head in normal movements; and

(ii) Three minutes exercising and running in place.

(3) The facepiece shall be capable of adjustment, according to the applicant's instructions, to each wearer's face, and the odor of isoamyl-acetate

shall not be detectable by any wearer during the test.

(c) Where the respirator is equipped with a full facepiece, hood, helmet, or mouthpiece, the canister or cartridge will be used in place of the filter unit, and persons will each wear the modified respiratory-inlet covering for 5 minutes in a test chamber containing 1,000 parts (by volume) of isoamyl-acetate vapor per million parts of air, performing the work schedule specified in paragraph (b)(2) of this section.

§ 84.1143 Dust, fume, and mist air-purifying filter tests; performance requirements; general.

Dust, fume, and mist respirators will be tested in accordance with the schedule set forth in Table 13 of this subpart to determine their effectiveness as protection against the particulate hazards specified in Table 13.

§ 84.1144 Silica dust test for dust, fume, and mist respirators; single-use or reusable filters; minimum requirements.

(a) Three non-powered respirators with single-use filters will be tested for periods of 90 minutes each at a continuous airflow rate of 32 liters per minute.

(b) The relative humidity in the test chamber will be 20–80 percent, and the room temperature approximately 25° C.

(c) The test suspension in the chamber will not be less than 50 nor more than 60 milligrams of flint (99+ percent free silica) per cubic meter of air.

(d) The flint in suspension will be ground to pass 99+ percent through a 270-mesh sieve.

(e) The particle-size distribution of the test suspension will have a geometric mean of 0.4 to 0.6 micrometer, and the standard geometric deviation will not exceed 2.

(f) The total amount of unretained test suspension in samples taken during testing shall not exceed 1.5 milligrams for a non-powered air-purifying respirator.

(g) Three non-powered respirators with reusable filters will be tested and shall meet the requirements specified in paragraphs (a) through (f) of this section; each filter shall be tested three times: Once as received; once after cleaning; and once after recleaning. The applicant's instructions shall be followed for each cleaning.

§ 84.1145 Silica dust test; non-powered single-use dust respirators; minimum requirements.

(a) Three respirators will be tested.

(b) As described in § 84.1144, airflow will be cycled through the respirator by a breathing machine at the rate of 24 respirations per minute with a minute volume of 40 liters; a breathing machine cam with a work rate of 622 kg.-m.2/minute shall be used.

(c) Air exhaled through the respirator will be 35° ±2° C. with 94 ±3 percent relative humidity. #

(d) Air inhaled through the respirator will be sampled and analyzed for respirator leakage.

(e) The total amount of unretained test suspension, after drying, in samples taken during testing, shall not exceed 1.8 milligrams for any single test.

§ 84.1146 Lead fume test for dust, fume, and mist respirators; minimum requirements.

(a) Three non-powered respirators will be tested for a period of 312 minutes each at a continuous airflow rate of 32 liters per minute.

(b) The relative humidity in the test chamber will be 20–80 percent, and the room temperature approximately 25° C.

(c) The test suspension in the test chamber will not be less than 15 nor more than 20 milligrams of freshly generated lead-oxide fume, calculated as lead (Pb), per cubic meter of air.

(d) The fume will be generated by impinging an oxygen-gas flame on molten lead.

(e) Samples of the test suspension will be taken during each test period for analysis.

(f) The total amount of unretained test suspension in the samples taken during testing, which is analyzed and calculated as lead (Pb), shall not exceed 1.5 milligrams of lead for a non-powered air-purifying respirator.

§ 84.1147 Silica mist test for dust, fume, and mist respirators; minimum requirements.

(a) Three non-powered respirators will be tested for a period of 312 minutes each at a continuous airflow rate of 32 liters per minute.

(b) The room temperature in the test chamber will be approximately 25°C.

(c) The test suspension in the test chamber will not be less than 20 nor more than 25 milligrams of silica mist, weighed as silica dust, per cubic meter of air.

(d) Mist will be produced by spraying an aqueous suspension of flint (99+ percent free silica), and the flint shall be ground to pass 99+ percent through a 270-mesh sieve.

(e) Samples of the test suspension will be taken during each test period for analysis.

(f) The total amount of silica mist unretained in the samples taken during testing, weighed as silica dust, shall not exceed 2.5 milligrams for a non-powered air-purifying respirator.

§ 84.1148 Tests for respirators designed for respiratory protection against more than one type of dispersoid; minimum requirements.

Respirators designed as respiratory protection against more than one particulate hazard (dust, fume, or mist) shall comply with all the requirements of this part, with respect to each of the specific hazards involved.

§ 84.1149 Airflow resistance tests; all dust, fume, and mist respirators; minimum requirements.

(a) Resistance to airflow will be measured in the facepiece, mouthpiece, hood, or helmet of a dust, fume, or mist respirator mounted on a test fixture with air flowing at a continuous rate of 85 liters per minute, both before and after each test conducted in accordance with §§ 84.1144 through 84.1147.

(b) The maximum allowable resistance requirements for dust, fume, and mist respirators are as follows:

MAXIMUM RESISTANCE

[mm. water-column height]

Type of respirator	Initial inhalation	Final inhalation	Exhalation
Pneumoconiosis- and fibrosis-producing dusts, or dusts and mists	12	15	15
Dust, fume, and mist, with single-use filter	30	50	20
Dust, fume, and mist, with reusable filter	20	40	20
Radon daughter	18	[1]25	15
Asbestos dust and mist	18	25	15

[1] Measured after silica dust test described in § 84.1144.

§ 84.1150 Exhalation valve leakage test; minimum requirements.

(a) Dry exhalation valves and valve seats will be subjected to a suction of 25 mm. water-column height while in a normal operating position.

(b) Leakage between the valve and valve seat shall not exceed 30 milliliters per minute.

§ 84.1151 DOP filter test; respirators designed as respiratory protection against dusts, fumes, and mists having an air contamination level less than 0.05 milligram per cubic meter and against radionuclides; minimum requirements.

(a) All single air-purifying respirator filter units will be tested in an atmosphere concentration of 100 micrograms of DOP per liter of air at continuous flow rates of 32 and 85 liters per minute for a period of 5 to 10 seconds.

(b) Where filters are to be used in pairs, the flow rates will be 16 and 42.5 liters per minute, respectively, through each filter.

(c) The filter will be mounted on a connector in the same manner as used on the respirator, and the total leakage for the connector and filter shall not exceed 0.03 percent of the ambient DOP concentration at either flow rate.

§ 84.1152 Silica dust loading test; respirators designed as protection against dusts, fumes, and mists having an air contamination level less than 0.05 milligram per cubic meter and against radionuclides; minimum requirements.

(a) Three non-powered respirators will be tested in accordance with the

provisions of §84.1144, or equivalent, and shall meet the minimum requirements of §§84.1144 and 84.1149.

(b) Three powered air-purifying respirators will be tested in accordance with the provisions of §84.1144 except they will be tested for a period of 4 hours each at a flowrate not less than 115 liters per minute to tight-fitting facepieces, and not less than 170 liters per minute to loose-fitting hoods and helmets. The total amount of unretained test suspension in samples taken during testing shall not exceed 14.4 milligrams for a powered air-purifying respirator with tight-fitting facepiece, and 21.3 milligrams for a powered air-purifying respirator with loose-fitting hood or helmet. They shall meet the minimum requirements of §84.1149.

§ 84.1153 Dust, fume, mist, and smoke tests; canister bench tests; gas masks canisters containing filters; minimum requirements.

(a) Gas mask canisters containing filters for protection against dusts, fumes, mists, and smokes in combination with gases, vapors, or gases and vapors, will be tested as prescribed in §84.1140 except for the breathing resistance which will be in accordance with §84.122.

(b) Gas mask canisters designed for protection against smokes will be tested in an atmospheric concentration of 100 micrograms of dioctyl phthalate per liter of air at continuous flow rates of 32 liters per minute and 85 liters per minute for a period of 5 to 10 seconds, and the DOP leakage through the canister shall not exceed 0.03 percent of the test concentration.

(c) Gas mask canisters containing filters for protection against dusts, fumes, mists, and smokes in combination with gases, vapors, or gases and vapors, will be tested as prescribed in §84.126.

§ 84.1154 Canister and cartridge requirements.

(a) Where two or more canisters or cartridges are used in parallel, their resistance to airflow shall be essentially equal.

(b) The color and markings of all canisters and cartridges or labels shall conform with the requirements of the American National Standards Institute, American National Standard for Identification of Air-Purifying Respirator Canisters and Cartridges, ANSI K13.1–1973. ANSI K13.1 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018. Copies may be inspected at the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

§ 84.1155 Filters used with canisters and cartridges; location; replacement.

(a) Particulate matter filters used in conjunction with a canister or cartridge shall be located on the inlet side of the canister or cartridge.

(b) Filters shall be incorporated into or firmly attached to the canister or cartridge and each filter assembly shall, where applicable, be designed to permit its easy removal from and replacement on the canister or cartridge.

§ 84.1156 Pesticide respirators; performance requirements; general.

Pesticide respirators and the individual components of each such device shall, as appropriate, meet the following minimum requirements for performance and protection:

(a) *Breathing resistance test.* (1) Airflow resistance will be measured in the facepiece, mouthpiece, hood, or helmet of a pesticide respirator mounted on a test fixture with air flowing at a continuous rate of 85 liters per minute, both before and after each test conducted in accordance with paragraphs (c) and (f) of this section.

(2) The maximum allowable resistance requirements for pesticide respirators are as follows:

MAXIMUM RESISTANCE
[mm. water-column height]

Type of pesticide respirator	Inhalation		Exhalation
	Initial	Final [1]	
Front- or back-mounted gas mask	70	85	20
Chin-style gas mask	65	80	20
Powered air-purifying [2]	[2] 50	[2] 70	20
Chemical Cartridge	50	70	20

[1] Measured at end of the service life specified in Table 14 of this subpart.
[2] Resistance of filter(s), cartridge(s), and breathing tube(s) only with blower not operating.

(b) *Facepiece test.* (1) The complete pesticide respirator will be fitted to the faces of persons having varying facial shapes and sizes.

(2) Where the applicant specifies a facepiece size or sizes for his respirator together with the approximate measurements of faces they are designed to fit, the Institute will provide test subjects to suit such facial measurements.

(3) Any pesticide respirator part which must be removed to perform the facepiece fit test shall be replaceable without special tools and without disturbing facepiece fit.

(4) The facepiece or mouthpiece fit test using positive or negative pressure recommended by the applicant and described in his instructions will be used during each test.

(5)(i) Each wearer will enter a chamber containing 1,000 p.p.m. isoamyl-acetate vapor for a respirator equipped with a full facepiece, mouthpiece, hood, or helmet and 100 p.p.m. isoamyl-acetate vapor for a respirator equipped with a half-mask facepiece.

(ii) The facepiece, mouthpiece, hood, or helmet may be adjusted, if necessary, in the test chamber before starting the test.

(iii) Each wearer will remain in the chamber while performing the following activities:

(A) Two minutes, nodding and turning head;

(B) Two minutes, calisthenic arm movements;

(C) Two minutes, running in place; and

(D) Two minutes, pumping with a tire pump into a 28-liter (1 cubic foot) container.

(iv) Each wearer shall not detect the odor of isoamyl-acetate during the test.

(c) *Silica dust test.* Three completely assembled pesticide respirators will be tested with a mechanical-testing apparatus as follows:

(1) Temperature in the test chamber will be approximately 25° C.

(2) Continuous airflow through the respirator will be 32 liters per minute for front-mounted, back-mounted, and chin-style gas mask pesticide respirators and chemical cartridge pesticide respirators, and not less than 115 (4 cubic feet) liters per minute to tight-fitting facepieces and 170 liters (6 cubic feet) per minute to loose-fitting hoods and helmets of powered air-purifying respirators.

(3) The test aerosol will contain 50–60 milligrams of 99+ percent free silica per cubic meter of air.

(4) The particle size distribution of the test suspension will have a geometric mean diameter of 0.4 to 0.6 micrometer, with a standard geometric deviation less than 2.

(5) Front-mounted, back-mounted, and chin-style gas mask pesticide respirators and chemical cartridge pesticide respirators will be tested for 90 minutes and powered air-purifying respirators will be tested for 4 hours.

(d) *Lead fume test.* Three completely assembled pesticide respirators will be tested with a mechanical-testing apparatus as follows:

(1) Continuous airflow through the respirator will be 32 liters per minute for front-mounted, back-mounted, and chin-style gas mask pesticide respirators and chemical cartridge pesticide respirators and not less than 115 liters (4 cubic feet) per minute, for powered air-purifying respirators with tight-fitting facepieces, and not less than 170 liters (6 cubic feet) per minute for powered air-purifying respirators with loose-fitting hoods and helmets.

(2) The test aerosol will contain 15–20 milligrams of freshly generated lead-oxide fume, calculated as lead, per cubic meter of air.

(3) The fume will be generated by impinging an oxygen-gas flame on molten lead.

(4) Front-mounted, back-mounted, and chin-style gas mask pesticide respirators and chemical cartridge pesticide respirators will be tested for 90 minutes and powered air-purifying pesticide respirators will be tested for 4 hours.

(5) The total amount of unretained test suspension, which is analyzed and calculated as lead, shall not exceed:

(i) 0.43 milligram for any 90-minute test;

(ii) 4.8 milligrams for any 4-hour test made at 115 liters (4 cubic feet) per minute; or

(iii) 6.2 milligrams for any 4-hour test made at 170 liters (6 cubic feet) per minute.

(e) *Dioctyl-phthalate test.* (1) All canisters submitted for use with front-mounted and back-mounted gas mask pesticide respirators will be tested in an atmospheric concentration of 100 micrograms of dioctyl-phthalate per liter of air at continuous flow rates of 32 and 85 liters per minute for a test period of 5 to 10 seconds.

(2) The DOP leakage through the canister shall not exceed 0.03 percent of the ambient DOP concentration.

(f) *Bench tests for pesticide respirators.* (1)(i) Bench tests will be made on an apparatus that allows the test atmosphere at 50±5 percent relative humidity and at room temperature (25°±2.5° C.) to enter the canister or cartridge at predetermined concentrations and rates of flow, and that has a means for determining the test life of the canister or cartridge against carbon tetrachloride.

(ii) Canisters and cartridges will be tested as they are used on each pesticide respirator, either singly or in pairs.

(iii) Three canisters or cartridges or pairs of cartridges will be removed from containers and tested as received from the applicant.

(iv) Two canisters, cartridges, or pairs of cartridges will be equilibrated at room temperature by passing 25 percent relative humidity air through them at the following flow rates (expressed as liters per minute (l.p.m.)) for 6 hours:

Type of canister or cartridge	Airflow rate, l.p.m.
Air-purifying canister	64
Air-purifying cartridge	25
Powered air-purifying with tight-fitting facepiece	115
Powered air-purifying with loose-fitting hood or helmet	170

(v) Two canisters, cartridges, or pairs of cartridges will be equilibrated at room temperature by passing 85 percent relative humidity air through them at the flow rates stated in paragraph (f)(1)(iv) of this section for 6 hours.

(vi) The equilibrated canisters or cartridges will be resealed, kept in an upright position at room temperature, and tested within 18 hours.

(2) Canisters and cartridges tested in accordance with the provisions of this section shall meet the requirements specified in Table 14 of this subpart.

§ 84.1157 Chemical cartridge respirators with particulate filters; performance requirements; general.

Chemical cartridge respirators with particulate filters and the individual components of each such device shall, as appropriate, meet the following minimum requirements for performance and protection:

(a) *Breathing resistance test.* (1) Resistance to airflow will be measured in the facepiece, mouthpiece, hood, or helmet of a chemical cartridge respirator mounted on a test fixture with air flowing at a continuous rate of 85 liters per minute, both before and after each test conducted in accordance with paragraphs (d) through (f) of this section.

(2) The maximum allowable resistance requirements for chemical cartridge respirators are as follows:

MAXIMUM RESISTANCE
[mm. water-column height]

Type of chemical cartridge respirator	Inhalation		Exhalation
	Initial	Final [1]	
For gases, vapors, or gases and vapors, and dusts, fumes, and mists	50	70	20
For gases, vapors, or gases and vapors, and mists of paints, lacquers, and enamels	50	70	20

[1] Measured at end of service life specified in Table 11 in subpart L of this part.

(b) *Facepiece test.* The facepiece test will be conducted as specified in § 84.205.

(c) *Lacquer and enamel mist tests; general.* (1) Three respirators with cartridges containing or having attached to them, filters for protection against mists of paints, lacquers, and enamels shall be tested in accordance with the provisions of paragraph (f) of this section.

(2) In addition to the test requirements set forth in paragraph (c)(1) of this section, three such respirators will be tested against each aerosol in accordance with the provisions of paragraphs (d) and (e) of this section.

(d) *Lacquer mist test.* (1) Temperature in the test chamber will be approximately 25° C.

(2) Continuous airflow through the respirator will be 32 liters per minute for air-purifying respirators, and not less than 115 liters per minute to tight fitting facepieces and 170 liters per minute to loose-fitting hoods and helmets of powered air-purifying respirators.

(3) Airflow through the chamber will be 20–25 air changes per minute.

(4) The atomizer employed will be a No. 64–5 nozzle with setup 3, or equivalent, operating at 69 kN/m.^{2} (10 pounds per square inch gage).

(5) The test aerosol will be prepared by atomizing a mixture of one volume of clear cellulose nitrate lacquer and one volume of lacquer thinner. The lacquer described in Federal Specification TT–L–31, October 7, 1953, is an example of an acceptable lacquer. Copies of TT–L–31 may be inspected or obtained from the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888.

(6) The concentration of cellulose nitrate in the test aerosol will be 95–125 milligrams per cubic meter.

(7) The test aerosol will be drawn to each respirator for a total of 156 minutes for air-purifying respirators and 240 minutes for powered air-purifying respirators.

(8) The total amount of unretained mist in the samples taken during testing, weighed as cellulose nitrate, shall not exceed 5 milligrams for an air-purifying respirator, 28 milligrams for a powered air-purifying respirator with tight-fitting facepiece, and 41 milligrams for a powered air-purifying respirator with loose-fitting hood or helmet.

(e) *Enamel mist test.* (1) Temperature in the test chamber will be approximately 25° C.

(2) Continuous airflow through the respirator will be 32 liters per minute for air-purifying respirators, and not less than 115 liters per minute to tight-fitting facepieces and 170 liters per minute to loose-fitting hoods and helmets of powered air-purifying respirators.

(3) Airflow through the chamber will be 20–25 air changes per minute.

(4) The atomizer employed will be a No. 64 nozzle with setup 1A, or equivalent, operating at 69 kN/m.^{2} (10 pounds per square inch gage).

(5) The test aerosol will be prepared by atomizing a mixture of 1 volume of white enamel and 1 volume of turpentine. The enamel described in Federal Specification TT-E–489b, May 12, 1953, with amendment-1 of 9 November 1955 is an example of an acceptable enamel. Copies of TT-E–489b may be inspected or obtained from the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888.

(6) The concentration of pigment in the test aerosol, weighed as ash, will be 95–125 milligrams per cubic meter.

(7) The test aerosol will be drawn to each respirator for a total of 156 minutes for air-purifying respirators and 240 minutes for power air-purifying respirators.

(8) The total amount of unretained mist in the samples taken during testing, weighed as ash, shall not exceed 1.5 milligrams for any air-purifying respirator, 8.3 milligrams for a powered air-purifying respirator with tight-fitting facepiece, and 12.3 milligrams for a powered air-purifying respirator with loose-fitting hood or helmet.

(f) *Bench tests; gas and vapor tests.* (1) Bench tests will be made in accordance with §84.207 and tested cartridges shall meet the minimum requirements set forth in Table 11 of subpart L of this part. Cartridges will be equilibrated in accordance with paragraph (f)(2) of this section.

(2)(i) Two powered air-purifying cartridges or pairs of cartridges will be equilibrated at room temperature by passing 25 percent relative humidity air through them at the following flow rates (expressed in liters per minute (l.p.m.)) for 6 hours:

Type of cartridge	Airflow rate, l.p.m.
Powered air purifying with tight-fitting facepiece	115
Powered air purifying with loose-fitting hood or helmet	170

(ii) Two powered air-purifying cartridges or pairs of cartridges will be equilibrated by passing 85 percent relative humidity air through them at the flow rates stated in paragraph (f)(2)(i) of this section.

(iii) All cartridges will be resealed, kept in an upright position, at room temperatures, and tested within 18 hours.

§84.1158 Dust, fume, and mist tests; respirators with filters; minimum requirements; general.

(a) Three respirators with cartridges containing, or having attached to them, filters for protection against dusts, fumes, and mists, except the mists of paints, lacquers, and enamels, will be tested in accordance with the provisions of §84.1157(f).

(b) In addition to the test requirements set forth in paragraph (a) of this section, three such respirators will be tested, as appropriate, in accordance with the provisions of §§84.1141 through 84.1152; however, the maximum allowable resistance of complete dust, fume, and mist, and gas, vapor, or gas and vapor chemical cartridge respirators shall not exceed the maximum allowable limits set forth in §84.1157(a)(2).

TABLES TO SUBPART KK OF PART 84

TABLE 12—FACEPIECE TEST REQUIREMENTS

[42 CFR Part 84, Subpart KK]

Respirator types	Pressure tightness test [1]	Isoamyl acetate test	
		84.1141	84.1142
Dusts: Air Contamination Level not less than 0.05 mg/M^3 or 2 mppcf	X		
Fumes: Air Contamination Level not less than 0.05 mg/M^3	X	X	
Mists: Air Contamination Level not less than 0.05 mg/M^3 or 2 mppcf	X		
Dusts, Fumes, and Mists: Air Contamination Level less than 0.05 mg/M^3 or 2 mppcf, and radionuclides	X		X
Radon daughters	X	X	
Asbestos-containing dusts and mists	X		

[1] Test is required only where applicable.

TABLE 13—AIR-PURIFYING AND POWERED AIR-PURIFYING RESPIRATOR FILTER TESTS REQUIRED FOR APPROVAL

[42 CFR Part 84, Subpart KK]

Respirator types	Silica dust tests			Lead fume test 84.1146	Silica mist test 84.1147	DOP test 84.1151
	84.1144	84.1145	84.1152			
Dusts: Air Contamination Level not less than 0.05 mg/M³ or 2 mppcf	X					
Fumes: Air Contamination Level not less than 0.05 mg/M³				X		
Mists: Air Contamination Level not less than 0.05 mg/M³ or 2 mppcf					X	
Dusts, Fumes, and Mists: Air Contamination Level less than 0.05 mg/M³ or 2 mppcf, and radionuclides			X			X
Radon daughters	[1] X				[2] X	
Asbestos-containing dusts and mists	[2] X				[3] X	
Single use dust and mist respirators		[3] X			[3] X	

[1] For resistance only.
[2] For penetration only.
[3] Test required only where applicable.

TABLE 14—CARBON TETRACHLORIDE BENCH TESTS AND REQUIREMENTS FOR CANISTERS AND CARTRIDGES

[42 CFR part 84, Subpart KK]

Type of pesticide respirator	Test concentration p.p.m. CCl_4	Flow rate l.p.m.	Number of tests	Minimum life minutes[1]
Chest-mounted or back-mounted gas mask (as received)	20,000	64	3	12
Chest-mounted or back-mounted gas mask (equilibrated)	20,000	32	4	12
Chin-style gas mask (as received)	5,000	64	3	12
Chin-style gas mask (equilibrated)	5,000	32	4	12
Chemical Cartridge respirator (as received)	1,000	64	3	50
Chemical cartridge respirator (equilibrated)	1,000	32	4	50
Powered air-purifying respirator (tight-fitting facepiece, as received)	1,000	[2] 115	3	50
Powered air-purifying respirator (tight-fitting facepiece, equilibrated)	1,000	[2] 115	4	25
Powered air-purifying respirator (loose-fitting hood or helmet, as received)	1,000	[3] 170	3	50
Powered air-purifying respirator (loose-fitting hood or helmet, equilibrated)	1,000	[3] 170	4	25

[1] Minimum life will be determined at 5 p.p.m. leakage.
[2] The flow rate shall be the effective flow rate of the device, but shall be not less than 115 l.p.m.
[3] The flow rate shall be the effective flow rate of the device, but shall be not less than 170 l.p.m.

PART 85—REQUESTS FOR HEALTH HAZARD EVALUATIONS

Sec.

AUTHORITY: Sec. 8(g), 84 Stat. 1600; 29 U.S.C. 657(g) and sec. 508, 83 Stat. 803; 30 U.S.C. 957.

SOURCE: 37 FR 23640, Nov. 7, 1972, unless otherwise noted.

§ 85.1 Applicability.

This part 85 applies to health hazard evaluations requested by any employer or authorized representative of employees under section 20(a)(6) of the Occupational Safety and Health Act of 1970 or section 501(a)(11) of the Federal Mine Safety and Health Act of 1977.

This part is not intended to preclude the use of other channels of communication with the National Institute for Occupational Safety and Health to obtain information and technical assistance concerning toxic substances or physical agents.

[45 FR 2652, Jan. 14, 1980]

§ 85.2 Definitions.

Any term defined in the Occupational Safety and Health Act of 1970 or the Federal Mine Safety and Health Act of 1977 and not defined below shall have the meaning given it in the respective Acts. As used in this part:

OSH Act means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651, *et seq.*).

FMSH Act means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801, *et seq.*).

Authorized representative of employees means any person or organization meeting the conditions specified in § 85.3–1(e) (1), (2), or (3).

Employee has the same meaning as stated in the OSH Act and for the purposes of this part includes *miner* as defined in the FMSH Act.

Employer has the same meaning as stated in the OSH Act and for the purposes of this part includes *Operator* as defined in the FMSH Act.

Health hazard evaluation means the investigation and the determination of potentially toxic or hazardous effects of: (a) Any substance normally used or found in any place of employment to which the OSH Act is applicable, or (b) any substance or physical agent normally used or found in any place of employment to which the FMSH Act is applicable.

Investigation means a physical inspection of the place of employment under section 8 of the OSH Act or section 103 of the FMSH Act and includes inspection, sampling, observations, review of pertinent records, and other measurements reasonably necessary to determine whether any substance or physical agent found in the place of employment has potentially toxic or hazardous effects in the concentrations or levels used or found.

NIOSH means the National Institute for Occupational Safety and Health, Center for Disease Control, Public Health Service, Department of Health and Human Services.

NIOSH officer means a NIOSH employee who has been authorized by the Director, NIOSH, to conduct investigations according to this part.

Physical agent means any condition produced by the environment and/or work processes that can result in hazardous effects as defined in this section. Examples of physical agents are noise, temperature, illumination, vibration, radiation, and pressure.

Place of employment means any coal or other mine, factory, plant, establishment, construction site, or other area, workplace, or environment where work is performed by any employee of an employer.

Substance means any chemical or biological agent or dust which has the potential to produce toxic effects.

Toxic effects or *hazardous effects* are those effects which result in short- or long-term disease, bodily injury, affect health adversely, or endanger human life.

[45 FR 2652, Jan. 14, 1980]

§ 85.3 Procedures for requesting health hazard evaluations.

(a) Requests for health hazard evaluations should be addressed to the National Institute for Occupational Safety and Health as follows:

(1) *Requests from general industry*. Hazard Evaluations and Technical Assistance Branch, Division of Surveillance, Hazard Evaluations, and Field Studies, NIOSH, 4676 Columbia Parkway, Cincinnati, OH 45226.

(2) *Requests from mining industry*. Environmental Investigations Branch, Division of Respiratory Disease Studies, NIOSH, 944 Chestnut Ridge Road, Morgantown, WV 26505.

(b) Requests for health hazard evaluations shall be submitted in writing and signed by either: (1) The employer in whose place of employment the substance or physical agent is normally found, or (2) an authorized representative of employees (see § 85.3–1(e)) in the place of employment where the substance or physical agent is normally found.

[45 FR 2653, Jan. 14, 1980]

§ 85.3–1 Contents of a request for health hazard evaluation.

Each request for health hazard evaluation shall contain:

(a) The requester's name, address, and telephone number, if any.

(b) The name and address of the place of employment where the substance or physical agent is normally found.

(c) The specific process or type of work which is the source of the substance or physical agent, or in which the substance or physical agent is used.

(d) Details of the conditions or circumstances which prompted the request.

(e) A statement, if the requester is not the employer, that the requester is:

(1) An authorized representative or an officer of the organization representing the employees for purposes of collective bargaining; or

(2) An employee of the employer and is authorized by two or more employees employed in the same place of employment to represent them for purposes of these Acts (each such authorization shall be in writing and a copy submitted with the request for health hazard evaluation); or

(3) One of three or less employees employed in the place of employment where the substance or physical agent is normally found.

(f) A statement indicating whether or not the name(s) of the requester or those persons who have authorized the requester to represent them may be revealed to the employer by NIOSH.

(g) The following supplementary information if known to the requester:

(1) Identity of each substance or physical agent involved;

(2) The trade name, chemical name, and manufacturer of each substance involved;

(3) Whether the substance or its container or the source of the physical agent has a warning label; and

(4) The physical form of the substance or physical agent, number of people exposed, length of exposure (hours per day), and occupations of exposed employees.

NOTE: NIOSH has developed two forms entitled "Request for Health Hazard Evaluation" and "Request for Mining Health Hazard Evaluation" to assist persons in requesting evaluations. The forms are available upon request from the offices listed in § 85.3(a) (1) and (2) or from the Regional Consultant for Occupational Safety and Health in any Regional Office of the Department of Health and Human Services.

[45 FR 2653, Jan. 14, 1980]

§ 85.4 Acting on requests.

(a) Upon receipt of a request for health hazard evaluation submitted under this part, NIOSH will determine whether or not there is reasonable cause to justify conducting an investigation.

(b) If NIOSH determines that an investigation is justified, a NIOSH officer will inspect the place of employment, collect samples where appropriate, and perform tests necessary to the conduct of a health hazard evaluation, including medical examinations of employees.

(c) If NIOSH determines that an investigation is not justified, the requester will be notified in writing of the decision.

[45 FR 2653, Jan. 14, 1980]

§ 85.5 Authority for investigations.

(a) NIOSH officers who have been issued official NIOSH credentials (Form No. CDC/NIOSH 2.93) are authorized by the Director, NIOSH, under sections 20(a) (6) and 8 of the OSH Act and sections 501(a)(11) and 103 of the FMSH Act: To enter without delay any place of employment for the purpose of conducting investigations of all pertinent processes, conditions, structures, machines, apparatus, devices, equipment, records, and materials within the place of employment; and to conduct medical examinations, anthropometric measurements, and functional tests of employees within the place of employment as may be directly related to the specific health hazard evaluation being conducted. Investigations will be conducted in a reasonable manner, during regular working hours or at other reasonable times and within reasonable limits. In connection with any investigation, the NIOSH officers may question privately any employer, owner, operator, agent, or employee from the place of employment; and review, abstract, and duplicate records required by the Acts and regulations and any other related records.

(b) Areas under investigation which contain information classified by any agency of the United States Government in the interest of national security will be investigated only by NIOSH officers who have obtained the proper security clearance and authorization.

[45 FR 2653, Jan. 14, 1980]

§ 85.6 Advance notice of visits.

(a) Advance notice of visits to the place of employment may be given to expedite a thorough and effective investigation. Advance notice will not be given when, in the judgment of the NIOSH officer, giving such notice would adversely affect the validity and effectiveness of the investigation.

(b) Where a request in accordance with this part has been made by an authorized representative of employees, advance notice in accordance with paragraph (a) of this section will be given by NIOSH to the requester, the representative of the employees for purposes of collective bargaining if such representative is other than the requester, and to the employer.

(c) Where a request in accordance with this part has been made by any employer, advance notice will be given by NIOSH to the employer. Upon the request of the employer, NIOSH will inform the authorized representative of employees of the visit: *Provided*, The employer furnishes NIOSH in writing with the identity of such representative and with such information as is necessary to enable NIOSH promptly to inform such representative of the visit.

§ 85.7 Conduct of investigations.

(a) Prior to beginning an investigation, NIOSH officers shall present their credentials to the owner, operator, or agent in charge at the place of employment, explain the nature, purpose, and scope of the investigation and the records specified in §85.5 which they wish to review. Where the investigation is the result of a request submitted by an authorized representative of employees, a copy of the request shall be provided to the employer, except where the requester or any person authorizing the requester pursuant to §85.3–1(e)(2) has indicated that NIOSH not reveal his name to the employer, in which case a summary of the basis for the request shall be provided to the employer.

(b) At the commencement of an investigation, the employer should precisely identify information which can be obtained in the workplace or workplaces to be inspected as trade secrets. If the NIOSH officer has no clear reason to question such identification, such information shall not be disclosed except in accordance with the provisions of section 20(a)(6) and section 15 of the OSH Act or section 501(a)(11) of the FMSH Act. However, if NIOSH at any time questions such identification by an employer, not less than 15 days' notice to an employer shall be given of the intention to remove the trade secret designation from such information. The employer may within that period submit a request to the Director, NIOSH, to reconsider this intention and may provide additional information in support of the trade secret designation. The Director, NIOSH, shall notify the employer in writing of the decision which will become effective no sooner than 15 days after the date of such notice.

(c) NIOSH officers are authorized to collect environmental samples and samples of substances or measurements of physical agents (including measurement of employee exposure by the attachment of personal sampling devices to employees with their consent), to take or obtain photographs related to the purpose of the investigation, employ other reasonable investigative techniques, including medical examinations of employees with the consent of such employees, and to question privately any employer, owner, operator, agent, or employee. The employer shall have the opportunity to review photographs taken or obtained for the purpose of identifying those which contain or might reveal a trade secret.

(d) NIOSH officers shall comply with all safety and health rules and practices at the place of employment being investigated, and they shall provide and use appropriate protective clothing and equipment. In situations requiring specialized or unique types of protective equipment, such equipment shall be furnished by the employer.

(e) The conduct of investigations shall be such as to preclude unreasonable disruption of the operations of the employer's establishment.

[37 FR 23640, Nov. 7, 1972, as amended at 45 FR 2653, Jan. 14, 1980; 49 FR 4739, Feb. 8, 1984]

§ 85.8 Provision of suitable space for employee interviews and examinations; identification of employees.

An employer shall, in request of the NIOSH officer, provide suitable space, if such space is reasonably available, to NIOSH to conduct private interviews with, and examinations of, employees. NIOSH officers shall consult with the employer as to the time and place of the medical examination and shall schedule such examinations so as to avoid undue disruption of the operations of the employer's establishment. NIOSH shall conduct, and assume the medical costs of, examinations conducted under this part.

§ 85.9 Representatives of employers and employees; employee requests.

(a) NIOSH officers shall be in charge of investigations. Where the request for a health hazard evaluation has been made by an authorized representative of employees, a representative of the employer and a representative authorized by his employees who is an employee of the employer shall be given an opportunity to accompany the NIOSH officer during the initial physical inspection of any workplace for the purpose of aiding the investigation by identifying the suspected hazard. The NIOSH officer may permit additional employer representatives and such additional representatives authorized by employees to accompany him where he determines that such additional representatives will further aid the investigation. However, if in the judgment of the NIOSH officer, good cause has been shown why accompaniment by a third party who is not an employee of the employer is reasonably necessary to the conduct of an effective and thorough investigation of the workplace, such third party may accompany the NIOSH officer during the inspection: *Provided, however,* That access by such persons to areas described in paragraph (d) of this section shall be in accordance with the requirements of such provision, and access to areas described in paragraph (e) of this section shall be with the consent of the employer. A different employer and employee representative may accompany the officer during each different phase of an inspection if this will not interfere with the conduct of the investigation.

(b) NIOSH officers are authorized to resolve all disputes as to who is the representative authorized by the employer and employees for the purpose of this section. If there is no authorized representative of employees, or if the NIOSH officer is unable to determine with reasonable certainty who is such representative, he shall consult with a reasonable number of employees concerning matters directly related to the health hazard evaluation.

(c) NIOSH officers are authorized to deny the right of accompaniment under this section to any person whose conduct interferes with a fair and orderly physical inspection.

(d) With regard to information classified by an agency of the U.S. Government in the interest of national security, only persons authorized to have access to such information may accompany an officer in areas containing such information.

(e) Upon request of an employer, any representative authorized under this § 85.9 by employees in any area containing trade secrets shall be an employee in that area or an employee authorized by the employer to enter that area.

§ 85.10 Imminent dangers.

Whenever, during the course of, or as a result of, an investigation under this part, the NIOSH officer believes that there is a reasonable basis for an allegation of an imminent danger, NIOSH will immediately advise the employer and those employees who appear to be in immediate danger of such allegation and will inform appropriate representatives of the Department of Labor or the State agency designated under section 18(b) of the OSH Act.

[37 FR 23640, Nov. 7, 1972, as amended at 45 FR 2653, Jan. 14, 1980]

§ 85.11 Notification of determination to employers, affected employees and Department of Labor.

(a) Upon conclusion of an investigation, NIOSH will make a determination concerning the potentially toxic or hazardous effects of each substance or physical agent investigated as a result of the request for health hazard evaluation. At a minimum, the determination will: (1) Identify each substance or physical agent involved and describe, where appropriate, the concentrations or levels of the substance or physical agent found in the place of employment and the conditions of use, and (2) state whether each substance or physical agent has potentially toxic or hazardous effects in the concentrations or levels found, as well as the basis for the judgments.

(b) Copies of the determination will be mailed to the employer and to the authorized representatives of employees.

(c) Except as hereinafter provided, the employer shall post a copy of the determination for a period of 30 calendar days at or near the workplace(s) of affected employees. The employer shall take steps to insure that the posted determinations are not altered, defaced, or covered by other material during such period. The employer will not be required to post the determination if the employer requests that copies of the determination be mailed to affected employees and furnishes NIOSH with a list of the names and mailing addresses of the employees employed in the workplace(s) designated by the NIOSH Officer. In the latter event, NIOSH will mail such copies to affected employees at the mailing addresses provided by the employer.

(d) For purposes of this section, the term "affected employees" means those employees determined by NIOSH to be exposed to the substance(s) or physical agent(s) which is the subject of the health hazard evaluation.

(e) Copies of determinations made under the OSH Act will be forwarded to the Department of Labor and the appropriate State agency designated under section 18(b) of the OSH Act. Copies of determinations made under the FMSH Act will be forwarded to the Mine Safety and Health Administration of the Department of Labor; the Bureau of Mines, Department of the Interior; and the State agency which, in the judgment of NIOSH, would benefit the most from the information. If NIOSH determines that any substance or physical agent has potentially toxic or hazardous effects at the concentrations or levels at which it is used or found in a place of employment, and the substance or physical agent is not covered by a safety or health standard established under section 6 of the OSH Act or section 101 of the FMSH Act, NIOSH will immediately submit the determination to the Secretary of Labor, together with all pertinent criteria.

[37 FR 23640, Nov. 7, 1972, as amended at 45 FR 2653, Jan. 14, 1980]

§ 85.12 Subsequent requests for health hazard evaluations.

If a request is received for a health hazard evaluation in a place of employment in which an evaluation under this part was made previously, NIOSH may make another investigation if, as a result of the passage of time or additional information, another investigation would be consistent with the purposes of the Acts.

[45 FR 2654, Jan. 14, 1980]

PART 85a—OCCUPATIONAL SAFETY AND HEALTH INVESTIGATIONS OF PLACES OF EMPLOYMENT

Sec.

AUTHORITY: Sec. 8(g), 84 Stat. 1600; 29 U.S.C. 657(g) and sec. 508, 83 Stat. 803; 30 U.S.C. 957.

§ 85a.1 Applicability.

(a) Except as otherwise provided in paragraph (b) of this section, the provisions of this part apply to investigations of places of employment which are conducted by NIOSH under sections 20 and 8 of the Occupational Safety and Health Act of 1970 and sections 501 and 103 of the Federal Mine Safety and Health Act of 1977.

(b) The provisions of this part do not apply to those activities covered by part 85 of this chapter.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.2 Definitions.

Any term defined in the Occupational Safety and Health Act of 1970 or the Federal Mine Safety and Health Act of 1977 and not defined below shall have the meaning given it in the Acts. As used in this part:

(a) *OSH Act* means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*) and *FMSH Act* means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 *et seq.*).

(b) *Assistant Regional Director* means any one of the ten Occupational Safety and Health Administration Assistant Regional Directors for Occupational Safety and Health.

(c) *Informed consent* means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:

(1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;

(2) A description of any attendant discomforts and risks reasonably to be expected;

(3) A description of any benefits reasonably to be expected;

(4) A disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(5) An offer to answer any inquiries concerning the procedures; and

(6) An instruction that the person is free to withdraw his consent and to discontinue participation in the investigation any time without prejudice to the subject.

(d) *Investigation* means research projects, experiments, demonstrations, studies, and similar activities of NIOSH which are conducted under section 20 of the OSH Act and section 501 of the FMSH Act.

(e) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to such subject's participation in the particular activity or procedure.

(f) *NIOSH* means the National Institute for Occupational Safety and Health of the Center for Disease Control, Public Health Service, Department of Health and Human Services.

(g) *NIOSH authorized representative* means a person authorized by NIOSH to conduct investigations of places of employment, including any person that is fulfilling a contract agreement with NIOSH or is serving as an expert or consultant to NIOSH pursuant to the Act.

(h) *NIOSH Regional Office* means any one of the ten Department of Health and Human Services Regional Offices, the addresses of which are specified in §5.31 of title 45, Code of Federal Regulations.

(i) *Place of employment* means any coal or other mine, factory, plant, establishment, construction site, or other area, workplace or environment where work is performed by any employee of an employer.

(j) *MSHA District Office* means any one of the Mine Safety and Health Administration's District Offices.

(k) *BOM* means the Bureau of Mines, Department of the Interior.

(l) *Employee* has the same meaning as stated in the OSH Act and for the purposes of this part includes *miner* as defined in the FMSH Act.

(m) *Employer* has the same meaning as stated in the OSH Act and for the purposes of this part includes *operator* as defined in the FMSH ACT.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.3 Authority for investigations of places of employment.

(a) NIOSH authorized representatives who have been issued official NIOSH credentials are authorized by the Director, NIOSH, under sections 20 and 8 of the OSH Act, sections 501 and 103 of the FMSH Act, and this part. To enter without delay any place of employment for the purpose of conducting investigations of all pertinent processes, conditions, structures, machines, apparatus, devices, equipment, and materials within the place of employment; and to conduct medical examinations, anthropometric measurements and functional tests of employees within the place of employment as may be directly related to the specific investigation being conducted. Such investigations will be conducted in a reasonable manner, during regular working hours or at other reasonable times and within reasonable limits. In connection with any investigations, such NIOSH authorized representatives may question privately any employer, owner, operator, agent, or employee from the place of employment; and review, abstract, or duplicate employment records, medical records, records required by the Act and regulations, and other related records. In those instances where systems of records subject to review, abstraction or duplication are of a confidential nature, such as medical records, and are abstracted or duplicated, NIOSH will maintain such systems in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and the implementing regulation of the Department of Health and Human Services (45 CFR part 5b).

(b) Areas under investigation which contain information classified by any agency of the United States Government in the interest of national security will be investigated only by NIOSH authorized representatives who have obtained the appropriate security clearance and authorization.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.4 Procedures for initiating investigations of places of employment.

(a) Except as otherwise provided in paragraph (b) of this section, NIOSH authorized representatives will contact an official representative of the place of employment prior to any site visits and will provide the details of why an investigation of the place of employment is being conducted. Prior to the initiation of a site visit of a place of employment, representatives of the following organizations will be advised of the site visit and the reason for its conduct:

(1) The appropriate State agency designated under section 18(b) of the OSH Act, or if no State agency has been designated under the OSH Act and in the case of the FMSH Act, the State agency which, in the judgment of NIOSH, would benefit the most from the investigation's findings;

(2) If there is a local union at the place of employment, the local president, business manager or other appropriate individual;

(3) The appropriate Assistant Regional Director, when investigations are conducted under the OSH Act;

(4) The appropriate MSHA District Office; the Director, BOM, and the Assistant Director for Mining, BOM, when investigations are conducted under the FMSH Act.

(b) Advance notice of site visits will not be given to the place of employment or local union at the place of employment when, in the judgment of the NIOSH authorized representatives, giving such notice would adversely affect the validity and effectiveness of an investigation. Those individuals and organizations specified in §85a.4(a)(1), (a)(3) and (a)(4) will be notified prior to the initiation of such a site visit. After the site visit has been initiated, and, as soon as possible thereafter, the NIOSH authorized representatives will contact those individuals specified in §85a.4(a)(2) concerning the nature and details of the site visit.

(c) In those instances where site visits are not necessary to the conduct of an investigation, the NIOSH authorized representatives will contact an official representative of the place of employment either verbally or through a written communication and provide the details of why an investigation of the place of employment is being conducted. If appropriate, the NIOSH authorized representatives will contact

those individuals stipulated in paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) of this section about the nature and details of the investigation.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§85a.5 Conduct of investigations of places of employment.

(a)(1) Prior to beginning a site visit, NIOSH authorized representatives will present their credentials to the employer, owner, operator or agent in charge at the place of employment, explain the nature, purpose and scope of the investigation and the records specified in §85a.3 which they wish to review, abstract or duplicate.

(2) In those instances where site visits are not necessary to the conduct of an investigation and the initial contact is made verbally, NIOSH authorized representatives will, at the request of the employer, owner, operator or agent in charge at the place of employment, provide a written explanation of the nature, purpose and scope of the investigation and the records specified in §85a.3 which they wish to review, abstract or duplicate.

(b)(1) At the commencement of an investigation, the employer, owner, operator or agent in charge at the place of employment shall precisely identify that information which is trade secret and might be seen or obtained by the NIOSH authorized representatives during the investigation. If the NIOSH authorized representatives have no clear reason to question such identification, such information will not be disclosed by NIOSH in accordance with the provisions of section 15 of the OSH Act. Generally, NIOSH will not question trade secret designations; however, if NIOSH at any time does question such identification, not less than 15 days' notice to the employer, owner, operator or agent will be given of the intention to remove the trade secret designation from such information. The employer, owner, operator or agent may within that period submit a request to the Director, NIOSH, to reconsider this intention and may provide additional information in support of the trade secret designation. The Director, NIOSH, will notify the employer, owner, operator or agent in writing of the decision which will become effective no sooner than 15 days after the date of such notice.

(2) In those instances where the NIOSH authorized representative is a person fulfilling a contact agreement with NIOSH or is serving as an expert or consultant to NIOSH pursuant to the Act, the employer, owner, operator or agent in charge at the place of employment may, after advising the NIOSH contractor or consultant in writing, elect to withhold information deemed to be a trade secret from such a NIOSH authorized representative or prohibit entry into the area of the place of employment where such entry will reveal trade secrets. In those instances, where the subject information is needed or access to the area of the place of employment is necessary, in the judgment of NIOSH, to fulfill the goals of the investigation, NIOSH regular employees will then obtain the information or enter the subject area of the place of employment.

(c)(1) NIOSH authorized representatives will be in charge of site visits conducted pursuant to this part.

(2) Where there is a request by the representative of the State agency and/or employees, who were notified pursuant to §85a.4(a)(1) or §85a.4(a)(2) to accompany the NIOSH authorized representatives during the site visit of the place of employment, the NIOSH authorized representatives will allow this request if they determine that this will aid the investigation; or where, in the judgment of the NIOSH authorized representatives, good cause has been shown why accompaniment by a third party who is not an employee of the employer is reasonably necessary to the conduct of an effective and thorough site visit, they may permit such third party to accompany them during the site visit: *Provided however,* That access by such person(s) to areas described in §85a.5(c)(4) shall be in accordance with the requirements of such provision and access to areas containing trade secrets shall be with the consent of the employer, owner, operator or agent in charge at the place of employment.

(3) NIOSH authorized representatives are authorized to deny the right of accompaniment under this paragraph to

any person whose conduct in their judgment interferes with a fair and orderly site visit. In all instances, a representative of the employer shall be permitted to accompany the NIOSH authorized representatives during the site visit of the place of employment.

(4) With regard to information classified by an agency of the United States Government in the interest of national security, only persons authorized to have access to such information may accompany NIOSH authorized representatives in areas containing such information.

(d)(1) NIOSH authorized representatives are authorized: To collect environmental samples and samples of substances; to measure environmental conditions and employee exposures (including measurement of employee exposure by the attachment of personal sampling devices to employees with their consent); to take or obtain photographs, motion pictures or videotapes related to the purpose of the investigation; to employ other reasonable investigative techniques, including medical examinations, anthropometric measurements and standardized and experimental functional tests of employees with the informed consent of such employees; to review, abstract, and duplicate such personnel records as are pertinent to mortality, morbidity, injury, safety, and other similar studies; and to question and interview privately any employer, owner, operator, agency, or employee from the place of employment. The employer, owner, operator, or agency shall have the opportunity to review photographs, motion pictures, and videotapes taken or obtained for the purpose of identifying those which contain or might reveal a trade secret.

(2) Prior to the conduct of medical examinations, anthropometric measurements or functional tests of any employees, the NIOSH authorized representatives will obtain approval of the procedures to be utilized from the NIOSH Human Subjects Review Board and no employee examination, measurement or test will be undertaken without the informed consent of such employee.

(e) NIOSH authorized representatives will comply with all safety and health rules and practices at the place of employment and all NIOSH, Occupational Safety and Health Administration, and Mine Safety and Health Administration regulations and policies during a site visit and will provide and use appropriate protective clothing and equipment. In situations requiring specialized or unique types of protective equipment, such equipment shall be furnished by the employer, owner, operator or agent in charge at the place of employment.

(f) The conduct of site visits will be such as to preclude unreasonable disruption of the operations of the place of employment.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980; 49 FR 4739, Feb. 8, 1984]

§ 85a.6 Provision of suitable space for employee interviews and examinations.

An employer, owner, operator or agent in charge at the place of employment shall, on request of the NIOSH authorized representatives, provide suitable space at the place of employment, if such space is reasonably available, to NIOSH to conduct private interviews with, and medical examinations, anthropometric measurements and functional tests of employees. NIOSH authorized representatives will consult with the employer, owner, operator or agent as to the time and place of the private interviews, medical examination, anthropometric measurements and functional tests and will schedule same so as to avoid undue disruption of work at the place of employment. NIOSH will conduct the medical interviews, measurements, examinations and tests specified under this part at its own expense.

[41 FR 45002, Oct. 14, 1976]

§ 85a.7 Imminent dangers.

Whenever, during the course of, or as a result of, an investigation under this part, the NIOSH authorized representatives believe there is a reasonable basis for an allegation of an imminent danger, NIOSH will immediately advise the employer, owner, operator or agent in charge at the place of employment and those employees who appear to be in immediate danger of such allegation

and will inform the agencies identified in §85a.4(a)(1), (a)(3), and (a)(4).

[41 FR 45002, Oct. 16, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§85a.8 Reporting of results of investigations of places of employment.

(a)(1) Specific reports of investigations of each place of employment under this part, with identification of the place of employment, will be made available by NIOSH to the employer, owner, operator or agent in charge at the place of employment, with copies to the appropriate officials and Agencies notified pursuant to §85a.4(a). Prior to release of such reports, a preliminary report will be sent by NIOSH to the employer, owner, operator or agent for review for trade secret information and technical inaccuracies that may inadvertently be presented in the report. If requested in writing, the data used to compile the reports will be made available by NIOSH to the employer, owner, operator or agent in charge at the place of employment, except that data will not be released in a form that is individually identifiable.

(2) All specific reports of investigations of each place of employment under this part will be available to the public from the NIOSH Regional Consultant for Occupational Safety and Health in the appropriate NIOSH Regional Office.

(3) In certain instances, specific reports of investigations of each place of employment will not be prepared. In such instances, a closing conference at the place of employment will be conducted by the NIOSH authorized representatives and those individuals participating in the site visit to discuss the findings of the site visit and appropriate recommendations.

(b)(1) Any specific findings of individual employee medical examinations, anthropometric measurements and functional tests will be released by NIOSH authorized representatives to the company physician, private physician, or other person only pursuant to the written authorization of the employee; otherwise, the specific findings and other personal records concerning individuals will be maintained in accordance with 45 CFR part 5b and section 3 of the Privacy Act of 1974 (5 U.S.C. 552a). Notice of all NIOSH systems of records as defined in 45 CFR 5b.1(n) as a result of the investigations of places of employment pursuant to this part will be published in the FEDERAL REGISTER under Notices of Systems of Records for the Department of Health and Human Services.

(2) In cases where an employee shows positive significant medical findings, the employee and the physician(s) designated by the employee under §85a.8(b)(1) will be immediately notified by NIOSH.

(3) A summary of the findings of the examinations for each employee will be sent by NIOSH to the individual.

(c) The findings of a total investigation generally will be disseminated as part of NIOSH criteria documents, NIOSH technical reports, NIOSH information packets, scientific journals, presentations at technical meetings, or in other similar manners. These findings of a total investigation will be presented in a manner which does not identify any specific place of employment; however, it should be noted that the specific reports of investigations of each place of employment under this part are subject to mandatory disclosure, upon request, under the provisions of the Freedom of Information Act (5 U.S.C. 552).

[41 FR 45002, Oct. 14, 1976]

PART 86—GRANTS FOR EDUCATION PROGRAMS IN OCCUPATIONAL SAFETY AND HEALTH

Subpart A—General

Sec.

Subpart B—Occupational Safety and Health Training Grants

Subpart C—Occupational Safety and Health Direct Traineeships

AUTHORITY: Sec. 8(g), 84 Stat. 1600, 29 U.S.C. 657(g); sec. 21(a), 84 Stat. 1612, 29 U.S.C. 670(a).

SOURCE: 40 FR 29076, July 10, 1975, unless otherwise noted.

Subpart A—General

§ 86.1 Applicability.

The regulations of this part are applicable to the award of training grants and direct traineeships pursuant to section 21(a)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 670(a)(1)) to assist in providing an adequate supply of qualified personnel to carry out the purposes of the Act.

§ 86.2 Definitions.

Any term not defined herein shall have the same meaning as given it in the Act. As used in this part:

(a) *Act* means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*).

(b) [Reserved]

(c) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(d) *State* means a State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Trust Territory of the Pacific Islands.

(e) *Training* means job-specific skill development, the purpose of which is to provide qualified personnel to carry out the purposes of the Act.

[40 FR 29076, July 10, 1975, as amended at 47 FR 53012, Nov. 24, 1982]

§ 86.3 Inventions and discoveries.

Any grant award pursuant to § 86.14 or § 86.33 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

§ 86.4 Publications and copyrights.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose, of such materials and to authorize others to do so.

§ 86.5 Grant appeals procedure.

The informal Public Health Service procedure for resolution of post-award grant disputes set forth in subpart D of part 50 of this title and the Department post-award grant appeals procedure in 45 CFR part 16 are applicable to any award made pursuant to this part.

Subpart B—Occupational Safety and Health Training Grants

§ 86.10 Nature and purpose of training grants.

(a) *Long-term training project grant.* A long-term training project grant is an award of funds to an eligible institution or agency, hereinafter called the "grantee," to pay part or all of the costs of organized identifiable activities, hereinafter termed the "project," that are undertaken to establish, strengthen, or expand graduate, undergraduate, or special training, of persons in the field of occupational safety and health. Such grants may be used to support training in, for example, occupational medicine, industrial hygiene, industrial nursing and occupational safety engineering and the training of technicians and paraprofessionals in such areas.

(b) *Short-term training project grant.* A short-term training project grant is an award of funds to an eligible institution or agency, hereinafter called the "grantee," to pay part or all of the costs of organized identifiable activities, hereinafter termed the "project" that are undertaken to provide intensive training programs of less than 1 year for any one or a combination of the following purposes:

(1) To provide specialized instruction for occupational safety and health professional or career personnel which will increase their competence in an area in their respective fields.

(2) To prepare or expand the capabilities of occupational safety and health professional or career personnel for leadership roles as administrators or supervisors, and

(3) To prepare or expand the teaching capabilities of occupational safety and health professionals and career personnel.

(c) *Educational Resource Center Grant.* An educational resource center grant is an award of funds to an eligible institution or agency, hereinafter called the "grantee," to pay part or all of the costs of organized identifiable activities, hereinafter termed the "project," that are undertaken to provide for the combination of long-term and short-term training activities as described in § 86.13 (c).

[40 FR 29076, July 10, 1975, as amended at 42 FR 52401, Sept. 30, 1977]

§ 86.11 Eligibility.

(a) *Eligible applicants.* Any public or private educational or training agency or institution located in a state is eligible to apply for a grant under this subpart.

(b) *Projects eligible for long-term or short-term training grants or educational resource center grants.* Any project found by the Secretary to be a long-term training project within the meaning of § 86.10(a) or a short-term training project within the meaning of § 86.10(b) or an educational resource center grant project within the meaning of § 86.10(c) shall be eligible for a grant award. However, no applicant is eligible for assistance for a separate training project grant in any project period in which it receives an educational resource center grant. Nothing in the section shall prevent an existing training grant from being incorporated into an educational resource center grant award.

[40 FR 29076, July 10, 1975, as amended at 42 FR 52401, Sept. 30, 1977; 47 FR 53012, Nov. 24, 1982]

§ 86.12 Application for a grant.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.[1] The application shall contain a full and adequate description of the project and of the manner in which the applicant intends to conduct the project in accordance with the requirements of this subpart, and a budget and justification of the amount of grant funds requested, and such other pertinent information as the Secretary may require.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the

[1] Applications and instructions may be obtained from the Procurement and Grants Office, Centers for Disease Control, Atlanta, GA 30333.

regulations of this subpart and any additional conditions of the grant.

[40 FR 29076, July 10, 1975, as amended at 49 FR 38117, Sept. 27, 1984]

§ 86.13 Project requirements.

(a) An approvable application for a long-term training grant must contain each of the following, unless the Secretary determines that the applicant has established good cause for its omission.

(1) Provision of a method for development of the training curriculum and any attendant training materials and resources;

(2) Provision of a method for implementation of the needed training;

(3) Provision of an evaluation methodology, including the manner in which such methodology will be employed, to measure the achievement of the objectives of the training program; and

(4) Provision of a method by which trainees will be selected.

(b) In addition to the requirements set forth in paragraph (a) of this section, an approvable application for a short-term training grant must contain each of the following, unless the Secretary determines that the applicant has established good cause for its omission.

(1) Provision of a methodology to assess the particular skills, or knowledge that prospective trainees need to develop;

(2) Provision of at least 18 hours of formal instruction for a period of not less than 2½ days and not more than 1 academic year; and

(3) Assurances that no portion of the Federal funds will be used for (i) in-service training courses designed only for employees of a single agency, institution, or organization; (ii) correspondence courses; (iii) regular courses usually given for academic credit; or (iv) training the grantee's financial officers, program director, or the official who executed the application.

(c) In addition to the requirements set forth in paragraphs (a), (b)(1), and (b)(3) (ii), (iii) and (iv) of this section, an approvable application for an educational resource center grant must contain each of the following, unless the Secretary determines that the applicant has established good cause for its omission:

(1) A description, supported by appropriate documents, of cooperative arrangements to conduct an educational resource center among a medical school (with an established program in preventive or occupational medicine), a school of nursing, a school of public health or its equivalent, and a school of engineering or its equivalent. Other schools or departments with relevant disciplines and resources—e.g., toxicology, biostatistics, environmental health, law, business administration, education—may be represented and contribute as appropriate to the conduct of the total program.

(2) The identification of an educational resource center Director who possesses a demonstrated capacity for sustained productivity and leadership in occupational safety and health training who shall oversee the general operation of the educational resource center program and shall, to the extent possible, directly participate in training activities.

(3) A description of the full-time professional staff representing various disciplines and qualifications relevant to occupational safety and health and capable of planning, establishing, and carrying out or administering training projects undertaken by the educational resource center.

(4) A description of the training and research expertise, appropriate facilities and ongoing training and research activities in occupational safety and health areas.

(5) A description of its program for conducting education and training of occupational health physicians, occupational health nurses, industrial hygienists/engineers and safety personnel. There shall be full-time students in each of these core disciplines, with a goal of a minimum total of 30 full-time students. Training may also be conducted in other occupational safety and health career categories, e.g., industrial toxicology, biostatistics, epidemiology, and ergonomics. Training programs shall include appropriate field experience including experience with public health and safety agencies and labor-management health and safety activities.

(6) A specific plan for making an impact on the curriculum taught by relevant medical specialties, including radiology, orthopedics, dermatology, internal medicine, neurology, perinatal medicine, and pathology.

(7) A description of its program to assist other institutions or agencies located within the applicant's region including schools of medicine, nursing and engineering, among others, by providing curriculum materials and consultation for curriculum/course development in occupational safety and health, and by providing training opportunities for faculty members.

(8) A specific plan for preparing, distributing, and conducting courses, seminars and workshops to provide short-term and continuing education training courses for physicians, nurses, industrial hygienists, safety engineers and other occupational safety and health professionals, paraprofessionals and technicians, including personnel of labor-management health and safety committees, in the geographical region in which the educational resource center is located. The content and orientation of the curriculum/courses shall take into consideration and address problems relevant to the geographic region served. The goal shall be that the training be made available each year to a minimum of 200–250 trainees representing all of the above categories of personnel with priority given to providing occupational safety and health training to physicians in family practice, as well as in industrial practice, and industrial nurses. These courses shall be structured so that educational institutions, public health and safety agencies, professional societies or other appropriate agencies can utilize them to provide training at the local level to occupational safety and health personnel working in the workplace. Further, the educational resource center shall have a specific plan and demonstrated capability for implementing such training directly and through other institutions or agencies in the region including cooperative efforts with labor unions and industry trade associations where appropriate.

[40 FR 29076, July 10, 1975, as amended at 42 FR 52401, Sept. 30, 1977]

§ 86.14 Evaluation and grant award.

Within the limits of funds available for such purpose the Secretary may award grants to assist in the establishment and operation of those projects which will in his judgment best promote the purposes of section 21(a)(1) of the Act, taking into account:

(a) In the case of long-term training grants:

(1) The need for training in the area or areas of study outlined in the application;

(2) The degree to which the proposal represents a strengthening or expansion of the applicant's program in such areas;

(3) The record of the applicant's effectiveness in training in these or related areas as indicated, among other things, by the placement of its graduates;

(4) The competence of the project staff in relation to the service to be provided;

(5) The reasonableness of the budget in relation to the proposed project;

(6) The applicant's resources, including equipment, facilities, and funds, available for the project;

(7) The current and potential availability of students in the area of study to be offered and their prospective employability as a result of the proposed training;

(8) The extent to which the applicant expects to absorb faculty positions initiated as a result of the grant; and

(9) The degree to which the project adequately provides for the requirements set forth in § 86.13(a).

(b) In the case of short-term training:

(1) The relationship of the contents of the course to the current and emergency training needs to carry out the purposes of the Act;

(2) The qualifications of the instructional staff;

(3) The speed with which the training can be put to use by the persons proposed to be trained;

(4) The reasonableness of the budget in relation to the proposed project;

(5) The success of previous offerings of this course, or related courses;

(6) Evidence of ability to recruit trainees and the estimated number to be enrolled during each course offering; and

(7) The degree to which the proposed project adequately provides for the requirements set forth in § 86.13(b).

(c) In the case of educational resource center grants:

(1) The criteria set forth in paragraphs (a) and (b) of this section.

(2) The degree to which the proposed project adequately provides for the requirements set forth in § 86.13(c).

(d) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either (1) on the basis of his estimate of the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage, not to exceed 8 percent, of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as travel or supply costs) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(e) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which support is recommended.

(f) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application annually at such times and in such form as the Secretary may direct.

[40 FR 29076, July 10, 1975, as amended at 42 FR 52402, Sept. 30, 1977]

§ 86.15 Payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the project to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§ 86.16 Use of project funds.

(a) Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with section 21(a) of the Act, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed by subpart Q of 45 CFR part 74.

(b) Prior written approval by the Secretary of revision of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities, which in the case of short term training grants, includes any change in the course dates or training sites.

(c) Grant funds are available for trainee stipends and for tuition, including fees and instructional materials, for travel costs related to training allowances. Stipends and allowances may not be increased or be paid beyond the term of the stipend on account of vacation an individual might have been entitled to but did not take.

(d) Stipends may only be paid to a trainee who is a citizen of the United States, an alien lawfully admitted to the United States for permanent residence, or a permanent resident of Guam, American Samoa, or the Trust Territory of the Pacific Islands.

(e) In the case of short term training grants, stipends may not be paid to persons receiving lecture fees, salary, travel expenses, or payment in any form as members of the course instructional staff.

(f) Grant funds used for alterations and renovations shall be subject to the condition that the grantee shall comply with the requirements of Executive Order 11246, as amended, and with the applicable regulations prescribed pursuant thereto.

§ 86.17 Nondiscrimination.

(a) Attention is called to the requirements of title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d

et seq.) and in particular section 601 of such Act which provides that no person in the United States shall on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to, discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which applies to grants made under this subpart, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR part 80).

(b) Attention is called to the requirements of title IX of the Education Amendments of 1972 (86 Stat. 373, 20 U.S.C. 1681 *et seq.*) and in particular to section 901 of such Act which provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance.

(c) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

§ 86.18 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for interest earned on grant funds.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political sudivisions of the State. All grantees other than a State, as defined in this section, must return all interest earned on grant funds to the Federal Government.

(c) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section; and

(ii) Any credits for earned interest pursuant to paragraph (b) of this section; and

(iii) Any other amounts due pursuant to subparts F, M, and O of 45 CFR part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assignees by setoff or other action as provided by law.

§ 86.19 Human subjects; animal welfare.

No grant award may be made under this subpart unless the applicant has complied with:

(a) 45 CFR part 46 pertaining to the protection of human subjects; and

(b) Chapter 1–43 of the Department Grants Administration Manual[2] concerning animal welfare.

§ 86.20 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

§ 86.21 Applicability of 45 CFR part 74.

The provisions of 45 CFR part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this part to States and local governments as those terms are defined in subpart A of that part 74. The relevant provisions of the following subparts of part 74 shall also apply to grants to all grantee organizations under this part:

45 CFR PART 74

Subpart and Subject
A General.
B Cash depositories.
C Bonding and insurance.
D Retention and custodial requirements for records.
F Grant-related income.
G Matching and cost sharing.
K Grant payment requirements.
L Budget revision procedures.
M Grant closeout: Suspension, and termination.
O Property.
Q Cost principles.

Subpart C—Occupational Safety and Health Direct Traineeships

§ 86.30 Nature and purpose of direct traineeships.

A direct traineeship is an award of funds directly from the Federal Government to an individual (herein called the "trainee") for his subsistence and other expenses during a period in which he is acquiring training (a) in the occupational safety and health professions, (b) for research relating to occupational safety and health, or (c) for teaching in occupational safety and health.

§ 86.31 Eligibility; minimum requirements.

In order to be eligible for an award under this subpart an applicant must:

(a) Have been accepted by a public or private institution for the purpose of the activity for which the traineeship is sought.

(b) Be a U.S. citizen, an alien lawfully admitted to the United States for permanent residence or a permanent resident of Guam, American Samoa, or the Trust Territory of the Pacific Islands.

[40 FR 29076, July 10, 1975, as amended at 47 FR 53012, Nov. 24, 1982]

§ 86.32 Application for direct traineeship.

An application for a direct traineeship under this subpart shall be submitted to the Secretary at such times and in such form and manner as he may prescribe.[1] In addition to the information supplied by the applicant in his application, such further information may be required as is necessary to determine his or her qualifications.

[40 FR 29076, July 10, 1975, as amended at 49 FR 38117, Sept. 27, 1984]

§ 86.33 Human subjects; animal welfare.

Where the application is for training at a non-Federal institution, no award may be made under this subpart unless said institution has complied with:

(a) 45 CFR part 46 pertaining to the protection of human subjects; and

(b) Chapter 1–43 of the Department Grants Administration Manual[2] 068 concerning animal welfare.

§ 86.34 Evaluation and award of direct traineeships.

Within the limits of funds available for such purpose and subject to the regulations of this part, the Secretary

[2] The Department Grants Administration Manual is available for inspection at the Public Information Office of the several Department Regional Offices and available for purchase at the Government Printing Office, GPO Document No. 894–523.

[1] Applications and instructions may be obtained from the Procurement and Grants Office, Centers for Disease Control, Atlanta, GA 30333.

[2] See footnote 2 to § 86.19.

may award direct traineeships to those qualified applicants who are in his judgment best able to carry out the purpose of the traineeships taking into consideration the need for training in the area of study specified in the application.

§ 86.35 Payments.

(a) Individuals receiving awards shall be entitled to such stipends and allowances as the Secretary may designate, taking into account such factors as the needs of the program, the cost of living, and the availability of funds.

(NOTE: These are prescribed in chapter 3–140 of the Department Grants Administration Manual[2]).

(b) Payments of stipends and allowances will, at the discretion of the Secretary, be made directly to the trainee or to the sponsoring institution for payment directly to the trainee.

§ 86.36 Duration and continuation.

Direct traineeship awards may be made for varying periods not in excess of 2 years. The Secretary may make one or more continuation awards for an additional period if he finds that satisfactory progress is being made toward accomplishment of the purpose of the initial traineeship award. Additional support may be provided on appropriate justification after expiration of the period of support in the previous award.

§ 86.37 Terms and conditions.

All direct traineeship awards shall be subject to the following terms and conditions:

(a) Training must be carried out at an institution found by the Secretary to provide a well-rounded course of instruction in the particular area of training for which the traineeship is awarded.

(b) No direct traineeship may be utilized to compensate any trainee for personal services or employment on behalf of the United States or any person.

§ 86.38 Accountability.

Accountability for payments will be subject to such requirements as may be specified by the Secretary.

§ 86.39 Termination of direct traineeship.

(a) The Secretary may terminate a direct traineeship at any time upon request of the trainee.

(b) After reasonable notice to the trainee and an opportunity for the presentation of the trainee's views and relevant evidence, the Secretary may terminate any direct traineeship prior to the date it would otherwise expire upon a determination that the trainee's performance is unsatisfactory, that the trainee is no longer attending the sponsoring institution, or that he or she is unfit or unable to carry out the purpose of the traineeship.

(c) The views and evidence of the trainee shall be presented in writing unless the Secretary determines that an oral presentation is desirable.

PART 87—NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH RESEARCH AND DEMONSTRATION GRANTS

Sec.

AUTHORITY: Sec. 8(g), 84 Stat. 1600 (29 U.S.C. 657(g)), sec. 508, 83 Stat. 803 (30 U.S.C. 957).

SOURCE: 46 FR 58676, Dec. 3, 1981, unless otherwise noted.

§ 87.1 To which programs does this regulation apply?

This regulation applies to research and demonstration project grants under:

(a) Section 20(a)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)(1)) for the support of studies related to occupational safety and health, and

(b) Section 501 of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951) for the support of health research in mining. These grants are awarded and administered by the National Institute for Occupational Safety and Health, Centers for Disease Control, of the Public Health Service.

§ 87.2 Definitions.

As used in this regulation:

Demonstration project grant means an award of funds to an eligible applicant to assist in meeting the cost of conducting a demonstration, either on a pilot or full-scale basis, of the technical or economic feasibility or application of a new or improved procedure, method, technique, or approach that will further the research purposes described in §87.4.

Principal investigator for a research project, or *project director* for a demonstration project, means a single individual who is responsible for the scientific and technical direction of the project.

Research project grant means an award of funds to an eligible applicant to assist in meeting the costs of conducting an identified research activity or program, study, or experiment that will further the research purposes described in §87.4.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

§ 87.3 Who is eligible to apply for a grant under this part?

Any public or private agency or institution is eligible to apply for a grant under this part, except Federal agencies or institutions not specifically authorized by law to receive such a grant.

§ 87.4 For what purposes may grants be awarded?

(a) The Occupational Safety and Health Act authorizes grants for research, experiments, and demonstrations relating to occupational safety and health, including studies of the psychological factors involved. This authority includes projects to develop innovative methods, techniques, and approaches for dealing with occupational safety and health problems.

(b) The Federal Mine Safety and Health Act authorizes grants for research projects designed to:

(1) Improve working conditions and practices affecting health in coal or other mines and to prevent occupational diseases originating in the mining industry.

(2) Develop epidemiological information to (i) identify and define positive factors involved in occupational diseases of miners, (ii) provide information on the incidence and prevalence of pneumoconiosis and other respiratory ailments of miners, and (iii) improve health standards.

(3) Develop techniques for the prevention and control of occupational diseases of miners, including tests for hypersusceptibility and early detection.

(4) Evaluate the effect on bodily impairment and occupational disability of miners afflicted with an occupational disease.

(5) Study the relationship between coal or other mine environments and occupational diseases of miners.

(6) Study matters involving the protection of life and the prevention of diseases in connection with persons who, although not miners, work with or around the products of coal or other mines in areas outside of such mines and under conditions which may adversely affect the health and well-being of such persons.

(7) Develop effective respiratory equipment.

§ 87.5 What information must be included in the grant application?

The application must contain a complete description of the objective of the project and the plan for carrying out the research or demonstration, the name and qualifications of the principal investigator or project director and principal staff members, the total resources and facilities that will be available, and a justification of the amount of grant funds requested.

§ 87.6 How will grant applications be evaluated and the grants awarded?

(a) The Secretary may award grants to those applicants whose approved

projects will best promote the purposes of either the Occupational Safety and Health Act or the Federal Mine Safety and Health Act on the basis of an evaluation conducted by experts or consultants engaged for this purpose.

(b) This evaluation will take into account the scientific merit and significance of the project, the competency of the proposed staff in relation to the type of research or demonstration involved, the feasibility of the project, the likelihood of its producing meaningful results, the proposed project period, the adequacy of the applicant's resources available for the project, the amount of grant funds necessary for completion, and for mining grant applications, the recommendations of the Mine Health Research Advisory Committee.

(c) The Secretary may evaluate and approve two or more concurrent applications, each dealing with one or more specified aspects of the project, and make two or more concurrent grant awards for the project. This may be necessary when a project involves a number of different but related problems, activities, or disciplines which would require evaluation by different groups, or when support for a project could be more effectively administered by separate handling of various aspects of the project.

§ 87.7 For what period of time will grants be awarded?

(a) The notice of grant award specifies how long the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 3–5 years.

(b) Generally, the grant will initially be for 1 year and subsequent continuation awards will also be for 1 year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application, nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 87.8 How may a grantee use grant funds?

A grantee shall only spend funds it receives under this part according to the approved application and budget, the authorizing legislation, the terms and conditions of the grant award, the applicable cost principles specified in subpart Q of 45 CFR part 74, and the regulations of this part.

§ 87.9 Which other HHS regulations apply?

Several other regulations apply to grants under this part. These include, but are not limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure

45 CFR part 16—Procedures of the Departmental Grant Appeals Board

45 CFR part 46—Protection of human subjects

45 CFR part 74—Administration of grants

45 CFR part 75—Informal grant appeals procedures

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964

45 CFR part 81—Practice and procedure for hearing under part 80 of this Title

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

[49 FR 38117, Sept. 27, 1984]